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 I

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DECLARATION OF RICHARD A. DENISON

I, Richard A. Denison, declare as follows:

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

2. I am a Lead Senior Scientist in the Health Program at Environmental Defense Fund (EDF). I have held this position for 31 years. I hold a

Ph.D. in Molecular Biophysics and Biochemistry from Yale University (1982) and a B.A. in Chemistry from the University of California Santa Cruz (1976).

3. I have served on several panels of the National Academy of Sciences (NAS), including its Standing Committee on Emerging Science for Environmental Health Decisions and its Board on Environmental Studies and Toxicology. I also was a member of NAS' Committee to Develop a Research Strategy for Environmental, Health and Safety Aspects of Engineered Nanomaterials. I was a member of EDF's team that worked jointly with the DuPont Corporation to develop a framework governing responsible development, production, use and disposal of nanoscale materials. I also have testified numerous times before Congress.
4. I have attached my curriculum vitae as Attachment A.
5. 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.
6. I have attached excerpts from a copy of *Pathways 2025, EDF's Strategic Plan* as Attachment B. The Plan explains that one of the Health Program's goals is to significantly reduce exposure to high-risk chemicals in consumer products, water, and food. It also explains that

"EDF is working 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.

7. 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.
8. I understand one of my major goals at EDF to be informing our members and the public generally about chemical substances.
9. One major constraint on EDF's and my ability to obtain and share information with the public, and to communicate accurately about this information, is the fact 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. Specific examples follow that illustrate how this constraint has adversely affected EDF's and my ability to obtain, share and communicate with the public about chemical safety and risk information.

10. In 1997, EDF published *Toxic Ignorance*, which became a seminal report documenting the dearth of health and environmental safety information even for chemicals produced in the largest amounts in the U.S. I have attached that report as Attachment C. However, EPA has stated that there are hundreds of high-production-volume (HPV) chemicals on the TSCA Inventory and in commerce the identities of which are not public because they were claimed CBI. Hence, we could not then, and still cannot identify the extent to which safety information is lacking for these chemicals because there is no way to search for such information without access to a specific chemical identity.

11. In 2009, I published an EDF report called *Across the Pond*, which used a list of "substances of very high concern" identified by officials in the European Union and checked that list against chemical production information that EPA collected on a subset of chemicals on the TSCA Inventory to identify which of these high-concern substances were produced in the U.S. by which companies and in what locations. I have attached that report as Attachment D. I had to include the following prominent disclaimer in the report to flag a significant limitation in our analysis:

> Under TSCA, U.S. companies have wide latitude to claim information they report to EPA as confidential business information (CBI). EPA

rarely challenges such claims and must not publicly disclose information claimed as CBI. Thousands of chemicals are not included in the public version of the TSCA Inventory because their producers have claimed the chemical identities to be CBI. Similarly, companies can also hide their own identities by claiming their production or import of a chemical to be CBI. Hence, the chemicals and companies we list in this report represent only the subset that are not claimed CBI.

12. In 2014, I contributed to another EDF report and interactive map project titled *Toxics Across America*, which used a list of chemicals of concern identified by various authoritative bodies, again checking that list against the chemical production information collected by EPA, to identify which of these high-concern chemicals were produced in the U.S. by which companies and in what locations. I have attached that report as Attachment E. The accompanying map allowed users to see what chemicals were made in their locales. Because of the fact that the identities of many chemicals on the TSCA Inventory and in commerce are not public because they were claimed CBI, the report prominently noted: "Therefore, the information on hazardous chemicals presented in this report represents only a partial picture of the production and use of these chemicals in the U.S."

13. The lack of access to other information beyond chemical identities also hampers our ability to analyze and publicly communicate chemical

information. For example, in EDF's *Toxics Across America* report, we also had to note that there could be other companies and other manufacturing site locations tied to high-concern chemicals that were not identified in the report or shown on our map, because in submitting information to EPA that we relied on for our report, companies had claimed their own identities or the locations of their sites to be confidential. More generally, the lack of public knowledge of which companies make specific chemicals and where they are made constrains the ability of EDF as well as community groups and members of the public to identify where risks posed by those chemicals may be highest or most likely to occur.

14. Excessive claims of confidentiality lead to a lack of public access to information on which groups like EDF rely to analyze and communicate about chemical risks, and also constrain EPA's ability to fully communicate about the analyses it conducts and the decisions it makes to identify and address chemical risks. As a result, as EDF has noted in comments we have submitted to EPA, the public has less confidence in that information and in those decisions.[1]

[1] Comments on TSCA Inventory Update Reporting Modifications: Proposed Rule 75 Federal Register 49656-49707 (Friday, August 13, 2010). Submitted October

15. A few years ago I and others at EDF sought to determine which of a list of chemicals that are registered for use under the European Union's REACH Regulation, and which had recently been designated "substances of very high concern" under REACH, were being produced and used in the U.S. We found that nine of these chemicals were not listed on the public version of the TSCA Inventory. We could not conclude that they are not in U.S. commerce, however, because they could be among the approximately 17,800 chemicals on the Inventory the identities of which are not publicly disclosed due to CBI claims. We asked EPA if it could confirm whether or not those chemicals were on the confidential portion of the Inventory and were told it would not do so because that would be disclosing whether they are in U.S. commerce. Hence, even though the identities of these chemicals were already public and we knew they were actively being produced and used in the EU, EDF and the public were denied knowledge of their presence in U.S. commerce because a company may have at one point in the past 40 years claimed the identity of each chemical to be CBI.

12, 2010. Available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0187-0069.

16. In order to further EDF's mission of reducing chemical risks and providing more chemical information to the public, I believe EDF will likely publish additional reports on chemical substances in the future relying on chemical information collected and disclosed by EPA. Based on my experience, described above, those reports would be more complete and robust if EPA disclosed the specific chemical identities of more of the chemicals listed on the Inventory.

17. Having maximal access to the identities of chemicals being produced or used in the U.S. is essential to EDF's and my efforts to find information on potential chemical risks, analyze that information, and communicate the information to the public. EDF routinely uses and relies on both domestic and international websites, databases and programs that provide information on chemical use, hazard, exposure, risk, and regulation. The only reliable way to obtain such information is with knowledge of the specific identity of a chemical, in order to be able to search for such information.

18. Among the many sources of chemical information that require a specific chemical identity in order to search them are:

- the EU's REACH Regulation's database of registered chemicals;

- the Organization for Economic Cooperation and Development's (OECD) eChemPortal, which compiles information from dozens of member countries' chemical databases;

- ToxNet, which compiles dozens of federal databases such as the Hazardous Substances Data Bank (which provides a wealth of information such as on chemical hazards, uses, and regulations issued by different agencies); the Household Products Database (which identifies ingredients in 10,000 consumer products), and the Integrated Risk Information System (which houses hazard assessments for over 500 chemicals).

19. On August 25, 2010, I submitted comments to EPA, on behalf of EDF and other groups, supporting EPA's policy of reviewing, and in most cases denying, confidentiality claims for chemical identities in all health and safety studies, and in data from health and safety studies, submitted under TSCA, even if the chemical identities are not listed on the public Inventory. [2]

[2] Comments on EPA's Notice of General Practice of Reviewing Confidentiality Claims for Chemical Identities in Health and Safety Studies and Data from Health and Safety Studies Submitted Under the Toxic Substances Control Act, 75 Federal Register 29,754 (May 27,2010). Submitted August 25, 2010. Available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2010-0446-0005.

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

Dated: March 5, 2018

RICHARD A. DENISON

Denison
Attachment A

RICHARD ALLAN DENISON

Title and Address: Lead Senior Scientist
Environmental Defense Fund
1875 Connecticut Avenue, N.W., Suite 600
Washington, DC 20009 USA
Phone: (202) 387-3500
Email: rdenison@edf.org

EDUCATION

1976-1982	Ph.D.	Yale University, Molecular Biophysics and Biochemistry
1974-1976	B.A.	University of California at Santa Cruz, Chemistry
1971-1974		University of California at Los Angeles, English, Biology

CURRENT POSITION

Lead Senior Scientist, Environmental Defense Fund; began working at EDF in 1987

MAJOR CURRENT AND RECENT PROJECTS

Chemicals Policy and Scientific Analysis: Analyze and assist in the development of chemicals policies and supporting science at the state, national and international levels. Widely regarded as a leading expert on the Toxic Substances Control Act (TSCA) and the European Union's REACH Regulation. Central player in the passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act in June 2016, which overhauled TSCA for the first time since its adoption in 1976. Developed legislative proposals and information in support of reform of the Act. Now lead EDF's team working for strong implementation of the new TSCA. Author of numerous papers addressing chemicals policy reform needs at the state and federal levels. Testified in 2009, 2010 and 2013 before the House Committee on Energy and Commerce, and in 2011 and 2015 before the Senate Committee on Environment and Public Works, on the need for TSCA.

Served on the National Academy of Sciences' Standing Committee on Emerging Science for Environmental Health Decisions and its Board on Environmental Studies and Toxicology, and on the Green Ribbon Science Panel of California's Green Chemistry Initiative convened to provide advice to the State's health and environmental agencies on chemicals policies. Served on the U.S. Environmental Protection Agency's National Pollution Prevention & Toxics Advisory Committee (NPPTAC).

Oversight of the U.S. EPA Chemicals Assessment and Management Programs: Manage all aspects of EDF's contributions to and oversight of EPA's chemicals assessment and management activities. These have included implementation of the Lautenberg Act by EPA's Office of Chemical Safety and Pollution Prevention (OCSPP); chemical assessment activities conducted by EPA's Office of Research and Development's (ORD) IRIS and ToxCast programs; and EPA's chemical information disclosure activities. Previously oversaw EPA's *HPV Challenge*, its voluntary chemical hazard testing program, which EDF helped to create, and *ChAMP* (Chemical Assessment and Management Program). Developed a comprehensive critique of these past programs and their limitations, based on our reviews of test plans and data summaries submitted under the Challenge and EPA's assessments develop under ChAMP.

MAJOR AREAS OF RELATED PRIOR WORK

Identifying and Managing Nanotechnology Risks: Involved in technical, legal and policy aspects of efforts to promote responsible development of nanotechnology. Served on the National Research Council's "Committee to Develop a Research Strategy for Environmental, Health and Safety Aspects of Engineered Nanomaterials." Served on the Organization for Economic Cooperation and Development's (OECD) Working Party on Manufactured Nanomaterials. Peer reviewer of USEPA's Nanotechnology White Paper and Nanomaterial Research Strategy and the National Academy's review of the federal government's risk research strategy. Testified twice before the House Committee on Science and Technology on research and oversight needs for nanotechnology. Served on the NPPTAC Ad Hoc Interim Workgroup on Nanotechnology. Served as a technical expert in the development with DuPont Corporation of our joint Nano Risk Framework, which delineates a proactive, information-driven approach to addressing the potential risks of nanomaterials across their lifecycles.

International Chemicals Work: Participated for Environmental Defense Fund in the activities of the Chemicals Committee and the Existing Chemicals Task Force under the Organization for Economic Cooperation and Development (OECD) HPV SIDS Program. Analyzed impacts of the European Union's REACH Regulation and Canada's Chemicals Management Plan on U.S. policies, businesses and chemicals.

PRIOR RESEARCH AND PROFESSIONAL POSITIONS

1985-1987	Analyst, Oceans and Environment Program, Office of Technology Assessment, U.S. Congress: principal author of OTA assessment on Ocean Incineration; assistant director for OTA assessment of Wastes in Marine Environments
1984-1985	Congressional Fellow, Office of Technology Assessment
1982-1984	Postdoctoral Fellow, Microbiology and Immunology Department, University of California at San Francisco, Advisor: J. Michael Bishop
1976-1980	National Institutes of Health Predoctoral Trainee, Molecular Biophysics and Biochemistry Department, Yale University

CURRENT AND RECENT PROFESSIONAL APPOINTMENTS

2011-2016	Member, National Academy of Sciences' Standing Committee on Use of Emerging Science for Environmental Health Decisions
2009-2013	Member, National Academy of Sciences' Committee to Develop a Research Strategy for Environmental, Health and Safety Aspects of Engineered Nanomaterials
	Member, Green Ribbon Science Panel, Department of Toxic Substances Control, State of California
2009-2012	Member, National Academy of Sciences' Board on Environmental Studies and Toxicology
2008	Peer Reviewer, National Research Council's Review of the Federal Strategy for Nanotechnology-Related Environmental Health and Safety Research
2007-2008	Peer Reviewer, U.S. EPA's Nanotechnology White Paper and Nanomaterial Research Strategy

2007-2008 Member, Green Chemistry Science Advisory Panel, Department of Toxic Substances Control, State of California

2002-2008 Environmental NGO representative to the Existing Chemicals Task Force and the Working Party on Manufactured Nanomaterials, Organization for Economic Cooperation and Development (OECD); member of Steering Committees for Workshops and Policy Dialogues on Chemical Categories, Exposure Assessment, Integrated Chemicals Assessment Approaches, and Health and Safety Implications of Nanotechnology

2004-2006 National Pollution Prevention and Toxics Advisory Committee, Environmental Protection Agency's Office of Pollution Prevention and Toxics

PROFESSIONAL ORGANIZATIONS

2002-Present Member, American Chemical Society

RECENT PUBLICATIONS AND TESTIMONY

Denison, R.A., "Robust New Chemical Reviews Vital to Restoring Confidence in TSCA," *Chemical Watch* Global Business Briefing, June 2017.

Denison, R.A. (2017) "A Primer on the New Toxic Substances Control Act (TSCA) and What Led to It," Environmental Defense Fund, Washington, DC.

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Denison, R.A., "Chemical Safety Reform: Will the Center Hold?" *The Environmental Forum*, May/June 2014, The Environmental Law Institute, Washington, DC.

Sasso, A.R. and Denison, R.A. (2014) *Toxics Across America: Who Makes the Billions of Pounds of Toxic Chemicals Flowing Through the U.S. Economy Each Year*," Environmental Defense Fund, Washington, DC.

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Denison, R.A. (2010) Testimony before the U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Commerce, Trade, and Consumer Protection, at a hearing on H.R. 5820, the Toxic Chemicals Safety Act of 2010, held 29 July 2010, Washington DC.

Denison, R.A. (2009) "Comment on *Using Competition-Based Regulation to Bridge the Toxics Data Gap*," *Environmental Law and Policy Annual Review*, 39 ELR 10709 (Environmental Law Institute, Washington, D.C.).

Denison, R.A. (2009) Testimony before the U.S. House of Representatives Committee on Energy and Commerce, Subcommittee on Commerce, Trade, and Consumer Protection, at a hearing on Revisiting the Toxic Substances Control Act of 1976, held 26 February 2009, Washington DC.

Denison, R.A. (2009) "Ten Essential Elements in TSCA Reform," *Environmental Law Reporter*, 39(1), 39 ELR 10020 (Environmental Law Institute, Washington, D.C.).

Denison, R.A. (2008) *Across the Pond: Assessing REACH's First Big Impact on U.S. Companies and Chemicals*, Environmental Defense Fund, Washington, DC.

Denison, R.A. (2008) "Policy Options for Generating Information for Sound Chemicals Management," in *Options for State Chemicals Policy Reform: A Resource Guide*, Lowell Center for Sustainable Production, University of Massachusetts at Lowell, January 2008, pp. 35-68.

Walsh, S., Balbus, J.M., Denison, R., and Florini, K., "Nanotechnology: Getting it right the first time," *J. Cleaner Production*, 16 (2008): 1018-1020.

Balbus, J. et al. "Meeting Report: Hazard Assessment for Nanoparticles—Report from an Interdisciplinary Workshop," *Environ. Health Persp.* 115(11), November 2007: 1654-59.

Denison, R.A. (2007) Testimony before the U.S. House of Representatives Committee on Science and Technology at a hearing on Research on Environmental and Safety Impacts of Nanotechnology: Current Status of Planning and Implementation under the National Nanotechnology Initiative, held 31 October 2007, Washington, DC.

Denison, R.A. (2007) *High Hopes, Low Marks: A final report card on the High Production Volume Chemical Challenge*, Environmental Defense Fund, Washington, DC.

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Denison, R.A., "Getting Nanotech Right the First Time," *The Environmental Forum*, July/August 2005, The Environmental Law Institute, Washington, DC, p. 42.

Denison, R.A. (2005) Testimony before the U.S. House of Representatives Committee on Science and Technology at a hearing on Environmental and Safety Impacts of Nanotechnology: What Research is Needed?, held 17 November 2005, Washington, DC.

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Denison, R.A. (2004) *Orphan Chemicals in the HPV Challenge: A Status Report*, Environmental Defense Fund, Washington, DC.

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Denison
Attachment B

Pathways 2025

EDF Strategic Plan

EDF
ENVIRONMENTAL DEFENSE FUND®
Finding the ways that work

Mission

Environmental Defense Fund's mission is to preserve the natural systems on which all life depends.
Guided by science and economics, we find practical and lasting solutions to the most serious environmental problems.

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Updates and an interactive version of this document are available at edf.org/pathways2025

Pathways 2025

As we write, the floodwaters are receding, but they have left a permanent mark on the people of the Caribbean, Texas and Florida. Tens of millions in Asia and the Americas are coping with the devastation from historically powerful typhoons and hurricanes. Global climate change helped fuel these storms, yet the President of the United States and the head of the U.S. Environmental Protection Agency (EPA) try to cast doubt on that reality—while surrendering America's climate leadership and proposing to cripple EPA and demolish public health and environmental safeguards.

That's a snapshot of our geophysical and political world in late summer 2017, and it hints at some of the reasons Environmental Defense Fund decided to prepare this new strategic plan, *Pathways 2025,* two years ahead of schedule.

Mounting climate urgency, and a U.S. administration that refuses to see it, demand new leadership—an even stronger commitment to clean energy and emissions reduction from China, Europe and others; from companies and institutions; and from cities, states and citizens. Fortunately, in response to the new federal assault on clean air, clean water and ecosystem protections, we are also seeing an extraordinary upwelling of public support for core environmental values. We must work together to meet this critical moment.

Since 2014, when we published our last plan, *Blueprint 2020,* several other developments have also prompted a full rethink of our strategy. The Paris climate agreement established new global ambitions that will require tremendous effort to achieve. The United Kingdom's vote to leave the European Union, like the 2016 U.S. election, has deep implications for our work. And as more governments and nonprofit groups around the world ask EDF to consult on their challenges—and the solutions to those challenges require international approaches—our work continues to become more global.

Carl Ferenbach, Fred Krupp and Diane Regas

The most important development may be the wave of technological innovation that is empowering communities to take action—and driving a revolution in environmental protection. You'll see examples throughout *Pathways 2025*.

Many paths can take us where we need to go, and no group can do all that's needed. So we assessed the facts on the ground, identified allies and looked at how EDF is best positioned to help. We charted our paths to 2025 and beyond, setting five-year milestones for 2022 to measure progress and hold ourselves accountable. (For climate and air pollution, we set milestones for 2025 to align with some countries' commitments in the Paris Agreement.)

Working together, we can move to stabilize the global climate, build defenses against extreme weather, ensure food security and abundant oceans, and reduce exposure to air pollution and toxic chemicals. In these pages, we share that vision and introduce a few of the people who will help make this plan a reality. Please join us in creating a better future.

Carl Ferenbach
Chairman

Fred Krupp
President

Diane Regas
Executive Director

Hope and resilience

In 1963, there were fewer than 500 nesting pairs of bald eagles in the United States. The pesticide DDT was thinning the birds' eggshells, causing the number of chicks to plummet. After EDF helped win a U.S. ban on DDT in 1972, the bald eagle rebounded. In 2007, with some 10,000 nesting pairs, the iconic bird came off the endangered species list.[1] We're proud that today the U.S. Fish and Wildlife Service estimates there are 143,000 adult bald eagles in the United States.

The United States has made tremendous environmental progress over the past 50 years. The air most of us breathe is cleaner than it has been in decades, and the acid rain that once fell on our lakes and forests has been dramatically reduced.[2] Magnificent, once-endangered birds like the bald eagle and osprey are thriving.[3] And dozens of fish species—Gulf red snapper and grouper, Pacific halibut and rockfish—are on the rebound as well.[4]

Environmental Defense Fund is proud to have played a central role in achieving these hard-won goals. And we're pleased and grateful that leaders in Europe, Asia and the Americas are increasingly drawing on our expertise to help solve their most pressing environmental challenges.

But there is still so much to be done. More than 125 million Americans live in places with unhealthy air.[5] Thousands of U.S. communities are plagued by lead poisoning.[6] And the environmental gains of the recent past are at risk as the Trump administration does all it can to roll back climate action and dismantle the bipartisan protections that helped deliver that progress.

The latest science deepens our understanding of climate risk, and underscores the urgent need to rapidly reduce greenhouse gas emissions. And peoples' everyday experience—more lethal heat, more destructive wildfires, more powerful storms—commands us all to see that we're in the race of our lives.[7] So EDF is helping to rally the millions of women and men who agree that environmental values are core human values.

Our work is grounded in the rigor of the scientific method and the insights of economics, and it is also infused with

Hope and resilience

hope. We know that our solutions, if scaled in time, can help turn the corner to a safer climate, cleaner air and healthier communities. Our commitment to measurable outcomes can be seen in our work to build resilience in the face of climate change. It's not a glib assurance that people and nature can magically adapt, but a realistic assessment of how we can help communities and ecosystems survive and even thrive.

The well-being of people and nature rests upon a web of interconnections among EDF's four focus areas: Climate, Oceans, Ecosystems and Health. Well-managed ocean fisheries, for example, are better able to withstand the stress of climate change—and the futures of people everywhere depend on healthy oceans.[8] In turn, the climate will benefit from our Health program's work to reduce conventional air pollution *(see p. 37)*, as well as from our Ecosystems work to reduce overuse of fertilizer, which means less of the powerful greenhouse gas, nitrous oxide, entering the atmosphere *(see p. 33)*. And building natural infrastructure—wetlands, barrier islands, oyster reefs—helps make coastal communities more secure *(see p. 30).*

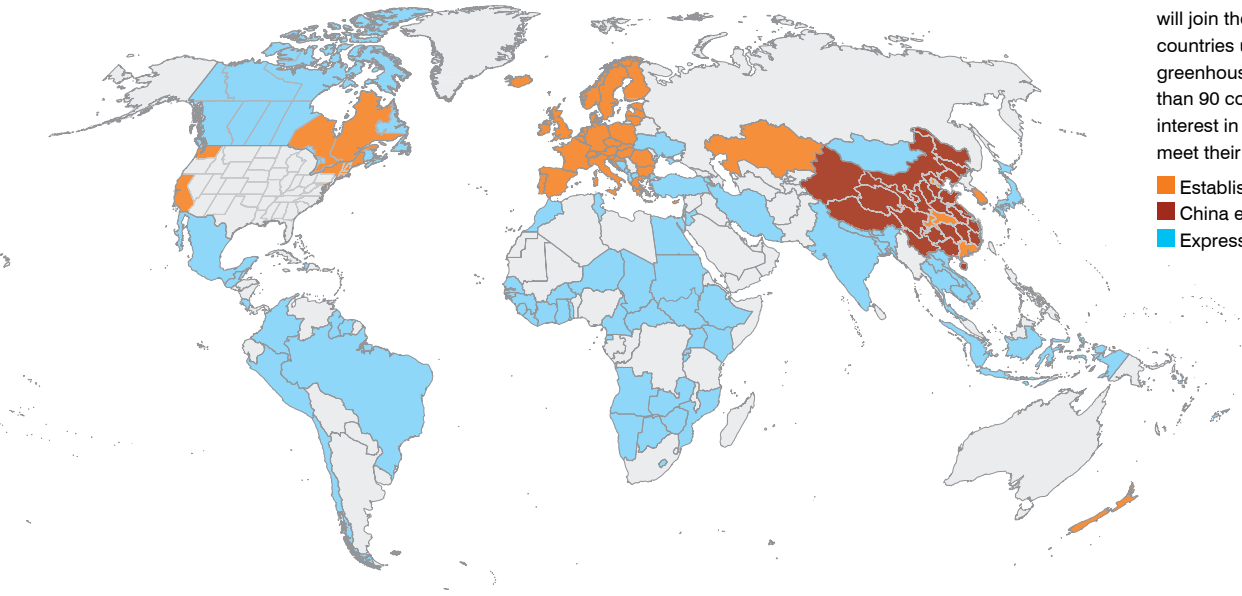
In the coming years, EDF will concentrate on strategies that drive progress despite the current roadblocks in Washington, DC. Our 11-year partnership

TWO DECADES IN CHINA

"EDF has gained a strong reputation and breadth of experience in protecting China's environment."

Dr. Zhang Jianyu
China Managing Director

Markets put a price on emissions



With the gradual expansion of its carbon trading pilot programs to a national carbon market, China will join the growing number of countries using markets to cut greenhouse gas emissions. More than 90 countries have expressed interest in using markets to help meet their Paris emission targets.

- Established markets
- China expansion
- Expressed interest

with Walmart helped inspire the world's largest retailer to commit to reducing one billion tons of carbon pollution from its operations and global supply chain by 2030—an amount greater than the annual emissions of Germany. And during more than 20 years of work in China, we have trained 39,000 environmental enforcement officers, championed tougher laws and offered assistance to the government as it rolled out seven pilot emissions trading programs to address carbon pollution.[9] These pilots gave China the confidence to begin phasing in a national emissions trading system for carbon in 2017. We'll work closely with the Chinese to ensure the success of this critical piece of global climate leadership *(see p. 12)*.

Similarly, EDF's work to rebuild fisheries is having a profound global impact. In the United States, fish populations are rebounding and fishermen are better off.[10] We have supported similar progress in Mexico, Belize, Sweden and the Philippines. Now we're scaling this work with a goal of reducing global overfishing 30% by 2025, in order to boost fish in the sea 50% by 2030 and improve the well-being of 400 million vulnerable people worldwide *(see p. 22)*.

EDF is known for building unexpected partnerships. Many elected officials and other decision makers had never seen such inclusive environmental coalition-building until we walked through their doors alongside fishermen, ranchers, corporate leaders and other unlikely allies. It makes for powerful first impressions—and durable solutions. Tens of thousands of consumer products are now safer because we partnered with Walmart and other retailers to remove chemicals of concern from them. We also supported a bipartisan coalition that passed landmark U.S. chemical safety legislation in 2016; now we're fighting for effective implementation of those critical reforms *(see p. 36)*.

On all of our issues, we apply the tools of science and economics, political acumen and technological innovation—harnessing the power of markets to drive environmental good. We call it finding the ways that work. It's the model you'll see throughout this plan, and together with your support, it's what gives us hope that we can build a resilient future where people and nature prosper.

SPOTLIGHT ON

Diversity

PROGRESS FOR ALL

"The communities harmed most by pollution are underrepresented in the environmental movement. This needs to change."

Ana Lucia Garcia Briones
Senior Specialist, California Groundwater, and Co-chair, EDF Diversity Committee

In the United States and around the world, EDF seeks to serve diverse communities, including the most vulnerable. We want everyone to enjoy environmental and economic well-being. Here are a few of our recent initiatives:

- Collaborating with 22 other national organizations after the Flint lead-poisoning crisis to accelerate replacement of the lead pipes that supply drinking water to up to ten million American homes.
- Working with Latino and low-income communities in California's Central Valley to improve water resource management.
- Helping rural communities in North Carolina gain access to clean energy.
- Training fishermen from marginalized communities in Belize to take on leading roles in the management of their fisheries.

Leadership

Sen. Lamar Alexander (R-TN) with national field manager Trisha Sheehan of our Moms Clean Air Force affiliate and her son Lincoln

Activating an environmental majority in America

Though EDF's focus is increasingly global, there is one area—political engagement—where our expertise and strategic emphasis continue to center on the United States, whose policies have global impact. EDF's work with policymakers and EDF Action's grassroots efforts will allow us to build a bench of environmental champions among both Republican and Democratic officials and to inspire a large, bipartisan majority of American voters to stand up for the bedrock value of environmental progress.

EDF Action, the U.S. political arm of Environmental Defense Fund, can freely lobby Congress and state legislatures thanks to the flexibility of donor support that is not tax-deductible.

The early months of the Trump administration saw a moment of genuine rebirth for the political salience of environmental issues—and a historic upwelling of support for our efforts. Hundreds of thousands took to the streets of Washington in the name of climate action and sound science. Donations to EDF and other organizations have set records. Polls show President Trump's environmental agenda is deeply unpopular.

EDF's vision At the federal level, our vision is of a Congress and administration in which members view undercutting environmental standards as carrying the same political risk as cutting Social Security. We seek to revive serious consideration of environmentally sound, market-based policy reforms for endangered species, climate, health and oceans.

At the state level, our vision is to have states leading the way on EDF's priorities when and where possible. State action played a crucial role in building pressure for toxic chemical policy reform, and places like Nevada and North Carolina are showing what is possible for clean energy outside traditionally progressive states. But there are dangers. State action in Oklahoma was the breeding ground for current EPA administrator Scott Pruitt, and organizations like the American Legislative Exchange Council (ALEC), funded by vested interests, have used state legislatures to set back our policy priorities.

Theory of change We believe that by engaging actively in the policymaking process, we can help build a durable and inclusive environmental majority in the United States. Since issues like clean air and water resonate strongly across the political spectrum, we have the chance to make our priorities relevant to members of Congress and other policymakers. They should view

politically active environmental organizations as fully equal to other powerful constituency groups in the United States.

The Trump administration has clearly set back our timeline on major issues. But the administration's extremism has also revealed deep public support for our positions, laying the groundwork for renewed political power. To turn this opportunity into a positive new chapter for environmental politics in America, we must use the tools we have built over the last few years: an EDF membership list of more than two million; our Moms Clean Air Force affiliate, with more than a million members; Defend Our Future, a burgeoning initiative to engage millennials; growing outreach to Latinos and conservatives; a multistate field program; and a powerful digital and earned media program that supports and amplifies all of these efforts.

In this moment of great peril, we are well positioned to take advantage of an energized citizenry to defend our environment, speak up for a world where people and nature prosper, and emerge strengthened for future progress.

OBJECTIVES FOR 2022

- Solutions are in place at the federal and state level that drive down greenhouse gas emissions, as a result of significant political support from people across the U.S. political spectrum.
- At the federal level and in targeted states, a diverse pro-environment majority supports environmental safeguards and protections for public health, supplying political power when needed to move forward on policies at either the executive or legislative level.
- There is a political cost to trying to tear down public health protections.
- A bench of new environmental champions has been elected in key states and at the federal level.

Some of our partners: American Security Project, Citizens' Climate Lobby, Congressional Hispanic Caucus Institute, Interfaith Power and Light, League of Conservation Voters, League of United Latin American Citizens, Niskanen Center, Natural Resources Defernse Council, Truman National Security Project, Young Conservatives for Energy Reform.[11]

SPOTLIGHT ON

Communications

THE VOICE OF REASON

"Persuasive communications are at the core of our work. Inspiring others to support and adopt great ideas helps turn them into reality."

Eric Pooley
Senior Vice President,
Strategy and Communications

As EDF program leaders formulated the strategies described in these pages, our communications experts began working to help achieve them. An increasingly global team of specialists in media relations, digital marketing, content production and member engagement helps us cut through the noise and build support for our solutions with the public, policymakers and a broad range of stakeholders.

We don't try to be the loudest voice in the room. As befits an organization founded by scientists, our tone is respectful, judicious and evidence-based. While some reject the idea that objective facts and analysis can change the world, EDF remains dedicated to reasoned, yet passionate, public debate and persuasion. That's who we are.

Health

REDUCING UNHEALTHY EXPOSURES

"We can secure a healthy future for our children and grandchildren if we take steps today to ensure the safety of chemicals and dramatically cut air pollution."

Dr. Sarah Vogel
Vice President, Health

Our vision of the future

People will enjoy healthier and more prosperous lives when we significantly reduce their exposure to pollution, including toxic chemicals and harmful air.

Imagine a future where decisions made about how we develop our communities—from the energy we use to the products we make—support the health and well-being of everyone.

That future is possible, but it is not the reality today. Everyday exposures to toxic chemicals and air pollutants increase the risks of heart and lung disease, adverse birth outcomes, reproductive problems and infertility, and learning and behavioral problems in children. That harms individuals, our economy and our society. According to the World Health Organization, air pollution alone results in six million premature deaths annually worldwide from heart attacks, cancer, strokes, respiratory disease and other causes.

Fortunately, technological innovation is providing new ways to make the invisible impacts of pollution visible, empowering communities to take action to protect public health. From low-cost sensors that improve our ability to measure and monitor environmental pollutants to rapid chemical testing technologies, EDF is working to transform data into meaningful, actionable information that will enable smarter policies and practices.

We are using tools that used to be reserved for governments and major corporations, and putting them in service of communities. We are building powerful nonpartisan coalitions, forging partnerships with companies and nonprofits alike, and advocating well-designed public policies that can drive down emissions and toxic chemical use, enhancing the lives of people young and old.

"In medicine the basic teaching is to 'do no harm.' EDF is working to prevent serious risks to our health and the health of future generations from exposure to air pollutants and toxic chemicals."

Richard Jackson, M.D., M.P.H.
Professor of Environmental Health Sciences, Fielding School of Public Health, University of California, Los Angeles
Former Director, National Center for Environmental Health, CDC

OUR CHILDREN DESERVE A HEALTHY START . . .

. . . AND THE FREEDOM TO JUST BE KIDS . . .

. . . THAT MEANS FORMULATING SAFER PRODUCTS . . .

. . . AND SECURING CLEANER AIR FOR EVERYONE.

EDF's health vision

Human health improves by reducing exposure to harmful chemicals and pollution.

2025 goal

Significantly reduce exposure to high-risk chemicals in consumer products, water and food, and be on track to reduce ambient air pollution globally.

Theory of change

By harnessing protections forged in law, and made possible by advances in information and technology, we can strengthen policies, expand civic engagement and advance supply chain practices that lead to reductions in exposures to harmful chemicals and air pollution.

Reduce exposure to toxic chemicals

Exposure to hazardous chemicals can contribute to serious health conditions including asthma, diabetes, childhood cancers, reproductive cancers and infertility—all of which are on the rise today. For too long, flawed public policies and corporate practices have failed to protect the public from harmful chemicals, or to create incentives to identify and reduce chemical risks.

EDF has been working to accelerate the incentives and increase the capacity to significantly reduce exposures to toxic chemicals. We have achieved remarkable progress, but in the current political environment it is now at risk.

After over a decade of effort by EDF, we have seen important progress on two fronts. In 2016, Congress passed a major overhaul to the chemical safety law that provides the federal government with the tools needed to improve the safety of chemicals. Major retailers like Walmart and Target are taking steps to reduce their chemical footprint and spur innovation in finding safer alternatives.[80]

Over the next five years, EDF will defend and strengthen public policies, continue to advance corporate leadership, and significantly expand actionable information on chemical risks. Protecting people—particularly the most vulnerable—from toxic chemicals demands strong federal safety standards, market leadership, greater access to actionable information and expanded civic engagement.

By aligning policies, markets and information systems, we can unlock a future where the food we eat, the water we drink and the products we use are safe and affordable.

Cadmium, Lead, Mercury, Benzene, 1,4-Dichlorobenzene, MTBE, Toluene, Cotinine, Perfluorooctanoic acid, Perfluorooctanyl sulfonate, Polybrominated diphenyl ethers (PBDE-47, PBDE-99, PBDE-100, PBDE-153), PCB-118, PCB-138 and -158, PCB-153, PCB-180, DDT, DDE, Hexachlorobenzene, Dimethylphosphate, Diethylphosphate, DMTP, Diethylthiophosphate, Dimethyldithiophosphate, BPA, Triclosan, Benzophenone-3, Monobenzyl phthalate, Monoisobutyl phthalate, Mono-n-butyl phthalate, MEP, 9-Hydroxyfluorene, 2-Naphthol, 2-Hydroxyphenanthrene, 1-Hydroxypyrene, Perchlorate

Pregnant women are exposed to multiple chemicals of concern, as revealed by blood tests and other biometrics.[82]

OBJECTIVES FOR 2022

- Strong implementation of the Lautenberg Chemical Safety Act is back on track with timely and health-based decisions on chemicals, including restrictions of high-priority chemicals that present the greatest risks to vulnerable populations.
- Major reductions are achieved in exposures to at least three high-risk chemicals that present significant health risks to infants and children: lead (achieve a 50% drop in children's blood lead levels); phthalates (achieve a significant decline from 2016 national biomonitoring levels); and perchlorate (be on track to drop to 2005 levels).
- 25% of personal care and household products are reformulated with safer ingredients, removing more than 50 million pounds of chemicals of concern from store shelves, and this trend is expanded to other product categories including food.

Some of our partners: American Water Works Association, Chemical Footprint Project, Children's Environmental Health Network, Earthjustice, Elevate Energy, Walmart.[81]

Improve air quality around the world

Air pollution kills people, makes them sick, limits their ability to work and learn, and degrades ecosystems. All of this imposes costs on society. In 2015, air pollution caused at least six million premature deaths worldwide, two-thirds due to outdoor air pollution, with nearly half those deaths in China and India.[83] (By comparison, in 2015, HIV-AIDS, tuberculosis and malaria combined caused around three million deaths.)[84] And outdoor air pollution is expected to rise, with a death toll potentially as high as nine million by 2060.[85]

No one wants to breathe noxious air. And no nation wants to hamstring its economy or rob its citizens of their well-being. A healthy, prosperous future is one where people and nature thrive as air pollution declines.

Since the 1970s, the United States has seen a 70% decline in air pollutants while enjoying a more than 200% increase in GDP.[86] EDF has played a pivotal role in reducing air pollution, and we must defend and expand the policies and practices that made this possible. Globally, as China and India continue on paths of tremendous growth, they, too, are positioned to become leaders in innovation that decouples air pollution from development.

By aligning policies and incentives to drive reductions in multiple pollutants, our solutions address both poor health and climate change. To support these efforts, EDF is also working to help scale hyperlocal air pollution monitoring and mapping. By generating actionable data on air quality for communities around the world, we will build knowledge and political support to reduce emissions.

Our focus is on significantly reducing outdoor air pollution in the United States, India and China. All are leading greenhouse gas emitters; India and China face air pollution crises and have made commitments to reduce climate pollution.

OBJECTIVES FOR 2025

- Deep reductions in multiple air pollutants are secured in the United States that by 2025 annually prevent 15,000 deaths, more than one million missed school and work days and half a million asthma attacks.
- Hyperlocal air quality mapping is available to communities around the world, providing scientifically robust, actionable data to inform policy and civic innovations.
- India is on track to achieve compliance with National Ambient Air Quality Standards for conventional pollutants by 2030, while building capacity to address climate pollution.[87]
- Air quality is improved by 40% from 2013 levels in the Beijing-Tianjin area by 2020.

Some of our partners: Google Earth Outreach, Harvard Environmental Law Program, One Breath Partnership, Rice University.[88]

KEY EFFORTS OUTSIDE EDF

Provide consumers with reliable information on how to avoid hazardous exposures *(e.g., Silent Spring Institute)*

Research and analysis of the impacts of air emissions to inform practices and policies *(e.g., Clean Air Task Force)*

Support of clean air and safer chemical policies to prevent disease and disability *(e.g., Learning Disabilities Association)*[89]

Summary of program objectives

Unless noted, all climate and air pollution objectives are for the year 2025, to align with some countries' commitments in the Paris Agreement, and all other objectives are for the year 2022.

Leadership

- Solutions are in place at the federal and state level that drive down greenhouse gas emissions, as a result of significant political support from people across the U.S. political spectrum.
- At the federal level and in targeted states, a diverse pro-environment majority supports environmental safeguards and protections for public health, supplying political power when needed to move forward on policies at either the executive or legislative level.
- There is a political cost to trying to tear down public health protections.
- A bench of new environmental champions has been elected in key states and at the federal level.

China

- Carbon emissions from major industrial sources are capped, and China's total carbon emissions peak by 2025, five years ahead of China's Paris Agreement target.
- Air quality improves across the country, including a 40% reduction from 2013 levels of fine particulate matter (PM 2.5) in the Beijing-Tianjin area by 2020.
- China is spearheading low-carbon development in the Belt and Road countries, by expanding its carbon market to those nations.

North America

- The United States has achieved a 26% to 28% reduction in greenhouse gas emissions (from a 2005 baseline).
- North America has reduced methane emissions from the oil and gas sector consistent with a 45% reduction in global methane emissions from that sector.

Europe

- Europe has increased its commitment under the Paris Agreement, pledging to cut emissions more than the originally promised 40% by 2030 (from a 1990 baseline).
- Carbon pricing is effective in reducing emissions across all sectors, including through the EU-ETS and through ICAO and IMO for international aviation and shipping.
- European countries and companies have made strong commitments to reduce methane emissions, consistent with achieving a 45% global reduction by 2025.
- Accelerated adoption of clean energy in all sectors has reduced carbon emissions (against a 2017 baseline) while allowing for strong growth in the economy.

India

- Be on track to achieve compliance with National Ambient Air Quality Standards for conventional pollutants by 2030, while building capacity to address climate pollution.
- A low-carbon rural development policy is established, with solutions including clean biogas stoves and low-carbon farming techniques adopted by ten million households in six states and an established pathway to national coverage.

Forests in Brazil and the Amazon

- Zero net carbon dioxide emissions from deforestation are achieved for Brazil and the entire Amazon.

Accelerating change

- Global methane emissions from the oil and gas sector are cut 45% from 2012 levels.
- Be on track for half of all global CO_2 emissions to be covered by durable, declining limits achieved with a carbon price by 2030.
- An improved understanding is achieved of technologies and practices that may be used to remove CO_2 from the atmosphere.

- Nearly a third of the world's catch is under policies or practices that make sustainable fishing the norm.
- Breakthrough collaborations and innovations in technology and science accelerate widespread adoption of sustainable fishing.
- Key fisheries in Asia, South America and Europe have robust systems in place to address climate change impacts, including species range shifts.

Build resilient coastal communities

- $3.5 billion is being invested on an annual basis in the design or construction of sustainable natural infrastructure to reduce coastal risks.
- Community-based resilience planning is built into adaptation efforts in Louisiana as a model for the rest of the world. Learning from Louisiana's adaptation experience is actively considered in three other U.S. areas and two areas outside the country.
- An adaptive management system for large-scale sediment diversion on the lower Mississippi River is in place, taking advantage of improved monitoring technologies.

Rebalance water systems

- Sustainable groundwater management plans that improve ecosystems and include water trading are being implemented in at least three groundwater basins.
- At least two major water deals to reduce water diversions from the Colorado River provide for farmers' active participation in water markets and habitat restoration.
- Satellite-based measurement of agricultural water use is available at low cost through a web interface to farmers, water managers and others across the West.
- Water trading in California and Arizona is on track to double from 2016 levels by 2025.

Expand habitat on working lands

- The U.S. Endangered Species Act and compensatory mitigation requirements continue to protect habitat and wildlife.
- $1 billion is invested annually through habitat exchanges or their equivalent in the United States.
- Habitat exchanges are established in at least one country outside the United States.

Make fertilizer pollution obsolete

- Companies across the food supply chain adopt greenhouse gas or water quality targets that drive fertilizer management improvements on half of U.S. corn acreage.
- Nutrient balance is established as the standard metric for quantifying nitrogen loss from agriculture, and tools and incentives are provided to reduce that loss.
- A technology platform is launched that allows greater transparency and scientific rigor in tracking reductions in greenhouse gas emissions and improvements in water quality across the supply chain.
- 2018 Farm Bill reauthorization and administrative action align policy and spending to promote conservation, increase soil health and boost resilience on agricultural lands.

Reduce exposure to toxic chemicals

- Strong implementation of the Lautenberg Chemical Safety Act is back on track with timely and health-based decisions on chemicals, including restrictions of high-priority chemicals that present the greatest risks to vulnerable populations.
- Major reductions are achieved in exposures to at least three high-risk chemicals that present significant health risks to infants and children: lead (achieve a 50% drop in children's blood lead levels); phthalates (achieve a significant decline from 2016 national biomonitoring levels); and perchlorate (be on track to drop to 2005 levels).
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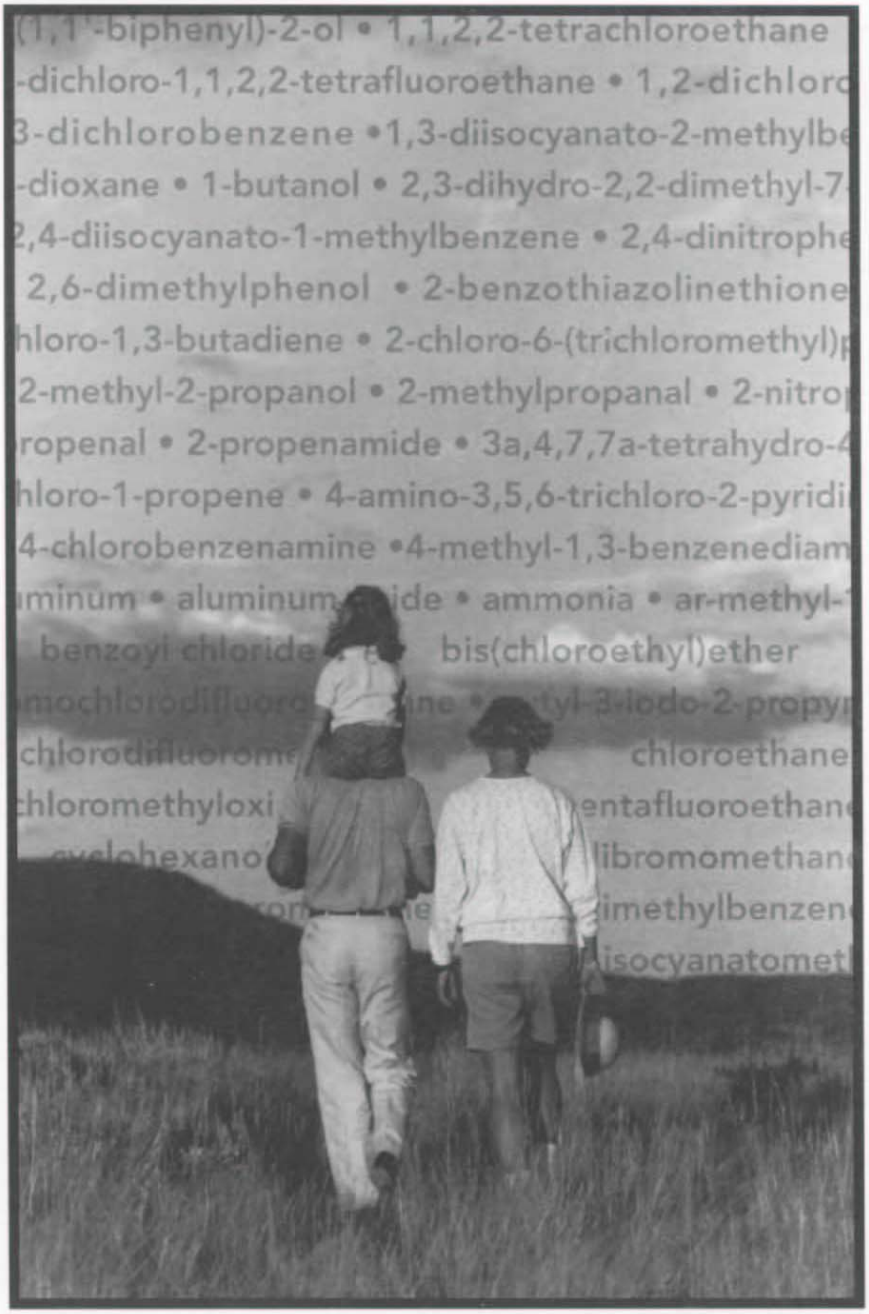
Denison
Attachment C

Toxic Ignorance



The Continuing Absence of Basic Health Testing for Top-Selling Chemicals in the United States

ENVIRONMENTAL DEFENSE FUND

ACKNOWLEDGMENTS

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Dr. William Pease designed and directed the research reported in Chapter II, which was carried out by Dr. Pease, Ken Leiserson, Curtis Below, Jean Chang, and David Abercrombie. The report was written by David Roe, Dr. Pease, Karen Florini, and Dr. Ellen Silbergeld. David Roe served as general editor. Kristin Lawton served as production manager and associate editor.

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COVER

The names of chemicals that appear on the cover are taken from the random sample of chemicals studied for this report, as described in Chapter II. They represent the group of sampled chemicals that are known to be emitted to the air from industrial facilities in the United States, as reported to the Toxics Release Inventory maintained by the U.S. Environmental Protection Agency.

EXECUTIVE SUMMARY

After DDT, after lead, after PCBs and other unintended chemical catastrophes, our knowledge about the chemicals we allow in commerce must have gotten much better. So Congress wrote into law, and so the public has a right to assume.

Yet for most of the important chemicals in American commerce, the simplest safety facts still cannot be found. Environmental Defense Fund research indicates that, today, even the most basic toxicity testing results cannot be found in the public record for nearly 75% of the top-volume chemicals in commercial use.

In other words, the public cannot tell whether a large majority of the highest-use chemicals in the United States pose health hazards or not — much less how serious the risks might be, or whether those chemicals are actually under control. These include chemicals that we are likely to breathe or drink, that build up in our bodies, that are in consumer products, and that are being released from industrial facilities into our backyards and streets and forests and streams.

In the early 1980s, the National Academy of Sciences' National Research Council completed a four-year study and found that 78% of the chemicals in highest-volume commercial use had not had even "minimal" toxicity testing. Thirteen years later, there has been no significant improvement.

What we don't know may not be hurting us — or it may. But guinea pig status is not what Congress promised the public more than twenty years ago. Instead, it established a national policy that the risks of toxic chemicals in our environment would be identified and controlled. Ignorance, pervasive and persistent over the course of twenty years, has made that promise meaningless.

Chemical safety can't be based on faith. It requires facts. Government policy and government regulation have been so ineffective in making progress against the chemical ignorance problem, for so long, that the chemical manufacturing industry itself must now take direct responsibility for solving it. It is high time for the facts to be delivered.

Step one toward a solution lies in simple screening tests, which manufacturers of chemicals can easily do. All chemicals in high-volume use in the United States should long since have been subjected to at least preliminary health-effects screening, with the results publicly available for verification. There is already international consensus on just what needs to be done as a first step. A model definition of what should be included in preliminary screening tests for high-volume chemicals was developed and agreed on in 1990 by the U.S. and the other member nations of the Organisation for Economic Cooperation and Development, with extensive participation from the U.S. chemical manufacturing industry. All that is missing is the industry's commitment to act, without waiting any longer.

Table of Contents

I. Introduction — the Dominance of Ignorance

After DDT, after lead, after PCBs and other unintended chemical catastrophes, our knowledge about the chemicals we allow in commerce must have gotten much better. So Congress promised with major laws, and so the public has a right to assume.

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Chapter II of this report, "The Current State of Ignorance about Chemical Hazards," presents detailed results of the Environmental Defense Fund's research. It reveals the absence in the public record of basic health screening data for high-volume chemicals in general; for chemicals with recognized potential for significant human exposure; and for chemicals

actually being released from industrial facilities today.

Chapter III, "The Failure of Federal Testing Requirements," analyzes and explains why 20 years of federal law and regulation have failed to require necessary testing to be performed.

Chapter IV, "Hints of Progress," examines some promising developments outside conventional law and regulation that begin to suggest how much faster progress could be encouraged.

Chapter V, "Recommendations," provides recommendations for legal and policy changes to produce much faster progress, consistent with the principle of direct responsibility of the chemical manufacturing industry itself to satisfy the public's need for basic safety information about chemicals in widespread commercial use.

II. The Current State of Ignorance About Chemical Hazards

The starting point for safe use of a chemical is, of course, knowing whether the chemical is toxic. This is known as **hazard identification**. There are many chemicals in circulation, and by no means are all of them toxic. Step one is to screen them, usually with quick and relatively inexpensive toxicity tests, to get a preliminary idea of which ones might be toxic and what forms of toxicity are involved (for example, a potential to cause cancer; or a potential to disrupt normal development of the fetus or child).

Analysis of the extent of health-hazard information on chemicals is rare. In 1980, the National Academy of Sciences' National Research Council began an extensive study to determine what need there was for additional toxicity testing. It concluded in 1984 that 78% of the chemicals in U.S. commerce with production volume of greater than one million pounds per year lacked even "minimal toxicity information."[1] This report is the first public attempt to update the 1984 findings on the extent of toxicity testing for chemicals in U.S. commerce.

A. Description of analysis and methods

Before presenting results, this section briefly describes the form of the analysis and the methods

used. A detailed description is presented in Appendix I.

1. Target category of chemicals

The chemicals addressed in this report do not include all, or even most, of the approximately 75,000 chemicals that the U.S. Environmental Protection Agency lists as being made in the U.S. in 1996.[2] This report covers only those chemicals that are produced in or imported into the U.S. in amounts greater than 1 million pounds per year (**high-production-volume chemicals**), as documented by the U.S. Environmental Protection Agency.[3] Because EPA's list does not include certain categories of chemicals, such as food additives, drugs, and pesticides, this study excludes those materials.

2. Analytical methods

This report uses the same approach as the 1984 National Research Council report, analyzing the availability of hazard identification data (i.e., toxicity testing results) by examining chemicals in a randomly selected representative sample[4] and then extrapolating the sample results to all high-production-volume chemicals.[5]

EDF drew its sample for this report from those chemicals that are *both* high-production-volume (more than 1,000,000 lbs./yr.), *and* have already been identified as subjects of regulatory attention under major environmental laws. Chemicals that turn up in both of these categories can fairly be considered to be **high-priority chemicals**, meaning chemicals with a high-priority need for hazard identification. Limiting the sample in this way makes it more likely to include chemicals that have been at least minimally tested, since a completely untested chemical is very unlikely to have been the subject of official regulatory focus. To the extent that this may introduce a bias in the results, it does so in favor of *overstating* the availability of information; i.e., the chemicals in the

sample are more likely to show adequate preliminary testing than chemicals in the entire high-production-volume group.

As in the 1984 report, the results from the sample are extrapolated to all 3,000 high-production-volume chemicals. This approach almost certainly overstates the degree of knowledge about hazard information for this larger group of chemicals, as explained above, and thus *under*states the actual degree of ignorance.

In measuring whether a chemical qualifies as having hazard identification data available, this report takes the internationally accepted definition of a minimum screening information data set that was created by the Organisation for Economic Cooperation and Development (OECD) Chemicals Program in 1990. It focuses only on the portion of the definition that covers screening for human health effects ("Toxicological Data"). These types of test data are shown in the accompanying box.

Toxicological Data

- Acute toxicity
- Repeated dose toxicity
- Genetic toxicity (*in vitro)*
- Genetic toxicity (*in vivo*)
- Reproductive toxicity
- Developmental toxicity/teratogenicity

If enough data to meet this portion of the OECD minimum screening requirements were found to be available for a particular chemical, it was assumed that an informed preliminary judgment about that chemical's potential human health hazards could be made.

There is international consensus that this data set represents the minimum amount of data required for a preliminary assessment of human health hazard of a chemical. However, it is important to note that the minimum screening information data set generally does *not* include enough data to conduct a comprehensive health risk assessment. It is only a starting point, and it is no substitute for the risk assessment that is called for under most major toxic chemical control laws. However, such a data set can be used to screen chemicals into different hazard categories with different priorities for next steps. Categories might include:

There is international consensus that this data set represents the minimum amount of data required.

- no further action;
- recommendations for further testing or exposure assessment to characterize risks more accurately; or
- recommendations to adopt control measures to reduce probable hazards.

3. Limitation to publicly available data

The analysis in this report uses only information from publicly available sources. For some chemicals there is undoubtedly private information as well: for example, tests on specific chemicals that major manufacturers have performed, or paid for, which to date have not been made available to the public. A specific example is discussed below at the end of this chapter. However, a report like this has no way to evaluate private data. More importantly, for purposes of assuring the public about the safety of specific chemicals, non-public data are of no real value. To rely on them is to ask the public to take chemical safety on faith — the exact opposite of the intent of modern toxic chemical control laws passed by Congress since 1970.

4. Limitation to high-production-volume chemicals

Focusing on chemicals with the highest production volume is one way to set priorities. This is the approach now being used by the OECD program that is trying to generate information about chemicals in commercial use. By focusing on the approximately 3,000 high-production-volume chemicals in U.S. commerce, this report aims at the ignorance problem where it should be least prevalent. Any chemical currently produced or imported in quantities of more than one million pounds per year should not have escaped the notice of its manufacturer or of regulators. In the absence of solid information to the contrary, use in such volume is presumably likely to be leading to

significant human exposures and releases to the environment.

The actual facts are particularly hard to establish for chemicals with no hazard identification data because, almost inevitably, such chemicals are not tracked or monitored. Proving whether people are being exposed to such chemicals or not is therefore extremely difficult.

B. Results

The results of EDF's analysis of the 100 chemicals in its random sample are illustrated in Figure 2-1. **Nearly three quarters (71%) of the sampled high-priority chemicals do not meet the minimum data requirements for health hazard screening set by the Organisation for Economic Cooperation and Development Chemicals Program.**

Thus, for the group of chemicals with the highest volume use in the United States, there is no basis for assurance that their use does not pose health risks to the American people, whether that assurance is offered by industry or by government.

Lack of meaningful assurance is not the same as proof of harm, of course. It is only proof of ignorance. But ignorance means that any conclusion about safety is unfounded. A system that relies on ignorance has no basis for inviting public confidence that chemical risks are under control — even from the chemicals being sold and used in the largest amounts. For approximately 75% of those chemicals, minimum critical information is lacking.

Of the potential health effects ("endpoints") that would be covered by minimum screening tests, a majority of chemicals in the high-priority sample have

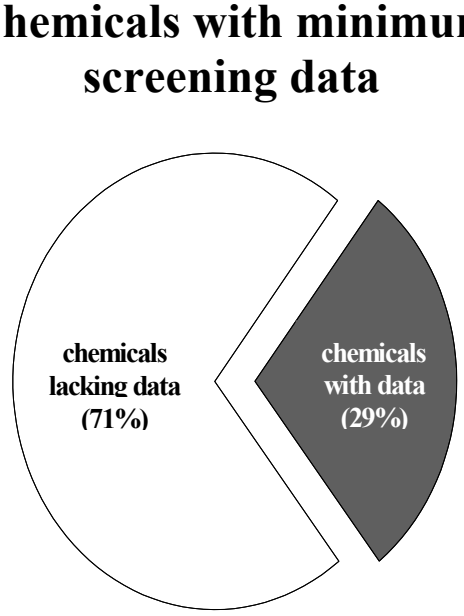


FIGURE 2-1

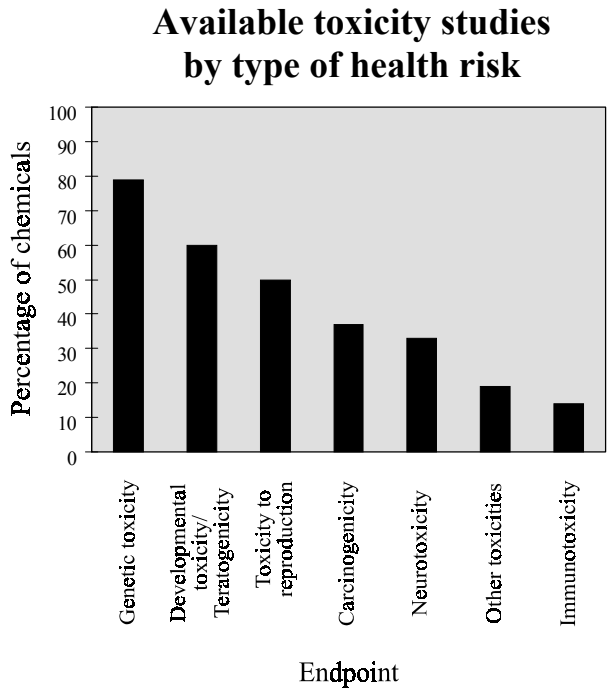


FIGURE 2-2

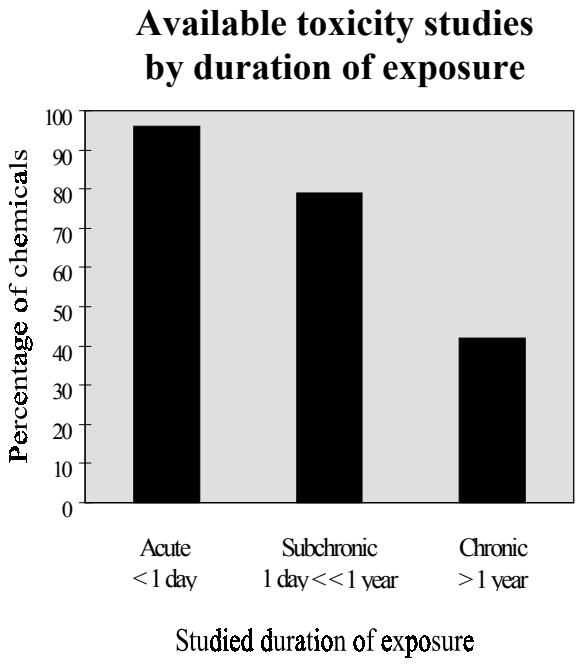


FIGURE 2-3

been tested for only two: genetic toxicity (i.e., ability to cause mutations) and developmental toxicity (e.g., ability to cause birth defects). Figure 2-2 illustrates.

Reproductive toxicity tests have not been conducted on 53% of high-priority chemicals. Carcinogenicity tests have not been conducted on 63% of high-priority chemicals. Neurotoxicity tests have not been conducted on 67%. Immunotoxicity tests have not been conducted on 86%. Endpoints of particular concern for evaluating impacts on children (such as postnatal performance and developmental neurotoxicity) have not been assessed for more than 90% of high-priority chemicals.

Exposure to these high-priority chemicals can occur from various sources, including from use of consumer products, from indoor or outdoor air, and in the workplace. In the workplace, use of chemicals can result in regular occupational exposures to production workers. Workplace use may also lead to ongoing exposures to the general public if these chemicals are released to the environment or are included in consumer products. To assess the safety of chemical use in such contexts, it is important to have data from chronic toxicity tests; i.e., tests investigating the effect of exposure to the chemical over substantial periods of time. Figure 2-3 illustrates that **more than half of the sampled high-priority**

chemicals have not been tested for any form of chronic toxicity.

For acute toxicity, by contrast, testing is much more likely to have occurred: over 90% of the sampled chemicals have been tested for some form of acute toxicity (usually death).

Most toxicity testing has not focused on the route of exposure that is most relevant for assessing human health risks. Both for the general public and for workers, the predominant route of exposure to many compounds is likely to involve breathing contaminated air (inhalation exposure). Yet more than two-thirds of high-priority chemicals have not been subjected to chronic inhalation tests that evaluate long-term air exposures to a toxicant.[6]

These results, for high-priority chemicals as a whole, are dismayingly meager. But an observer might raise the possibility that, despite their priority for regulators and their high volume of commercial use, the chemicals under study might not be representative of those actually out in the environment. Perhaps, for example, chemicals we are most likely to be exposed to outdoors have been tested, even if other high-volume chemicals have not. To test this possibility, EDF looked only at the chemicals in its sample that are reported on the national Toxics Release Inventory as being released by industry into the environment, a total of 47 chemicals.[7] The results are shown in Figure 2-4.

TRI chemicals: proportion with minimum screening data

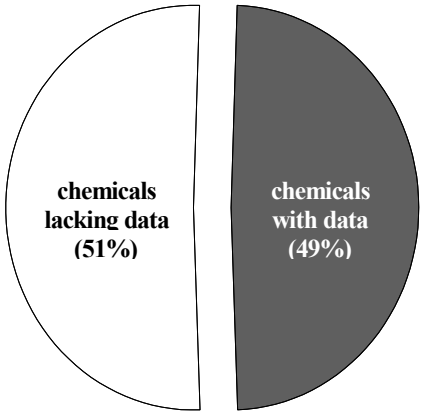


FIGURE 2-4

Even of the sampled chemicals that are *known* to be released into the environment, 51% do not meet minimum screening requirements for health hazard identification. This result is particularly

Chemicals with medium/high potential human exposure: proportion with minimum screening data

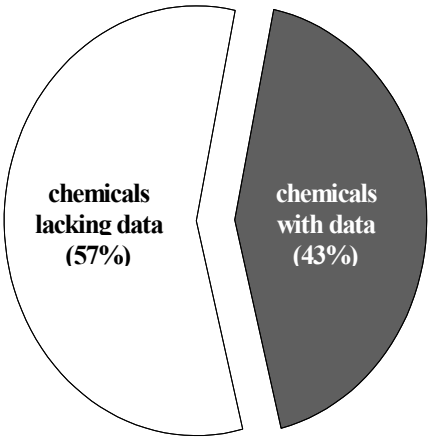


FIGURE 2-5

striking, since to be included on the Toxics Release Inventory a chemical must already have been found to be "toxic" on the basis of some evidence of harm. This finding illustrates an important point: that even with chemicals for which *one* health hazard may have been found, we are likely not to have even a preliminary idea whether *other* health hazards are also presented.

For the portion of the sampled chemicals for which we have especially strong reasons to anticipate human exposure, the results are similar. The U.S. EPA has established criteria for assessing the exposure potential of chemicals based on bioaccumulation and persistence; i.e., whether they are likely to build up in our bodies, and whether they are likely to last for a long time in the environment.[8] Looking only at sampled chemicals with "high" and "medium" exposure potential, a total of 42 chemicals, 57% do not meet minimum screening requirements for health hazard identification. This finding means that **chemicals with special likelihood of exposure have not been tested to any significantly greater degree than other chemicals.** Just because regulators can identify chemicals with special likelihood of exposure does not mean that better testing for their potential health effects has yet occurred, or that the results of any such testing are publicly obtainable.

C. Checking the accuracy of results

1. Partial review by two chemical companies

Large chemical manufacturers are likely to be particularly knowledgeable about the state of testing

on their own chemicals. EDF therefore asked the two companies which appeared to have the greatest number of chemicals in the random sample, Dow Chemical Co. and DuPont, to review the scoring of those chemicals that EDF used in deriving the results shown in Section B above.

On 15 of the 17 chemicals which Dow and DuPont agreed to review,[9] EDF's overall score and that of the company was the same. Dow and DuPont both confirmed that the categories in EDF's scoring approach accurately matched the relevant categories of the OECD screening program. Each company differed with EDF on the overall scoring[10] of one chemical, for reasons discussed below.

Dow's difference with the overall score of one of its chemicals was based on the existence of private studies of the chemical that are not available in the public literature. If scoring is limited to publicly available studies — as EDF's scoring necessarily was — then Dow's and EDF's overall scores are the same. However, Dow did not concur that private studies should be excluded from consideration.

As a caveat, Dow also noted that it believed another of its chemicals in the sample should be considered to have been adequately screened, notwithstanding a negative score based on a lack of testing on the chemical itself, because the structure of the chemical is sufficiently similar to other well-tested chemicals that expert toxicologists could reasonably draw conclusions about its safety. As an additional caveat, Dow noted that tests outside the categories established in the OECD screening process should in some cases be considered superior to OECD-required tests, and thus that a chemical could in fact have been adequately tested for screening purposes notwithstanding a negative score based on the lack of an OECD-required test.

DuPont's difference with the overall score of one of its chemicals was based on a publicly available study that EDF's research did not locate. EDF confirmed that the study was appropriate and adequate to change the relevant score; i.e., that DuPont was correct. EDF did not locate the study because it lay outside the boundaries of the computer search methodology that EDF used. (This occurred in part because no abstract of the study existed on any of the relevant computer databases.) EDF's computer search methodology is discussed in detail in Appendix I.

Although incomplete (covering only 17 out of 100 chemicals), this review by Dow and DuPont provides additional confidence that the scoring of chemicals in EDF's random sample is accurate enough to be used as representative of high-production-volume chemicals in general for purposes of this report.[11]

CHAPTER II NOTES

[1] National Research Council, Toxicity Testing (Washington, D.C.: National Academy Press, 1984), Table 7, p. 84. Findings for other categories of chemicals (e.g., chemicals with smaller production volume) are shown in the same table. The study's definition of "minimal toxicity information" appears in Table 3 on p. 47.

[2] As of October 1996, there were 75,857 chemicals in EPA's TSCA Inventory. The Inventory covers chemicals manufactured in the U.S., with certain important exceptions such as pesticides, food additives, and drugs. See discussion of TSCA in Chapter III.

[3] EPA's list can be obtained as digital media from the agency's Office of Pollution Prevention and Toxics. Pesticides and food additives are excluded from the listing as high-production-volume chemicals because of provisions in the Toxic Substances Control Act. Some chemicals are included in more than one of these categories.

[4] For analyzing the availability of hazard identification data, this report uses a sample of one hundred chemicals, the same size sample as used by the National Research Council in its 1984 study. See note 1 *supra*.

[5] The 1984 report presented results for other categories of chemicals as well. See note 1 *supra*.

[6] 74% of high-priority compounds have been tested using at least one acute inhalation study; 50% have been examined using exposures lasting longer than 24 hours; and only 32% have been examined using lifetime inhalation exposures.

[7] The Toxics Release Inventory is discussed in more detail in Chapter IV below.

[8] U.S. Environmental Protection Agency, Office of Solid Waste and Office of Pollution Prevention and Toxics, Waste Minimization Prioritization Tool, Beta Test Version 1.0, User's Guide and System Documentation, Draft (Washington, D.C.: U.S. EPA, 1997), Exhibit B-1, p. B-1. Internet/WWW [address: http://www.epa.gov/epaoswer/hazwaste/minimize/tool/tooldown.htm].

[9] EDF initially identified 25 chemicals in its sample as Dow or DuPont chemicals, using the National Library of Medicine's Hazardous Substances Data Bank and the 1996 Directory of Chemical Producers: USA compiled by SRI International. However, for seven of the chemicals, the companies informed EDF that manufacturing of the chemical had either ceased or had been transferred to another entity (i.e., that the HSDB or SRI information was out of date). For one additional chemical, Dow informed EDF that it was inappropriate to consider Dow responsible for the chemical because it was manufactured on contract for a non-Dow business entity.

[10] Each chemical in the random sample first received yes-or-no scores for each of six categories of hazard identification testing. Those were then combined into an overall yes-or-no score for each chemical, indicating whether or not there had been sufficient testing to satisfy the OECD screening requirements. For the chemicals reviewed by Dow or DuPont, they agreed with EDF on 99 out of 108 scores for individual categories. Eliminating differences based on private studies or structural analogies to other chemicals (see text), which EDF intentionally excluded, there was agreement on 104 of 108 scores.

[11] Dow and DuPont each participated willingly and generously in this review. However, each company's participation was limited to reviewing the scoring of its own chemicals for purposes of satisfying the OECD screening requirements. Neither company should be understood to have made any judgment about the scoring of any chemicals other than its own, or about the significance of satisfying or not satisfying the OECD requirements. As indicated above, the companies believe that other forms of information, apart from the information scored by EDF, is also relevant to identification of chemical hazard.

III. The Failure of Federal Testing Requirements

Chemical safety is the opposite side of the same coin as chemical risk. Both require knowledge before they can be demonstrated. A system that is very slow in testing chemicals for their hazards is, necessarily, even slower in being able to establish their safety.

Yet assurance of safety is the purpose of toxic chemical control laws.[12] This is the public's understanding, and also the understanding of the chemical industry; "safe" is the term commonly used by the chemical industry to describe its products and activities.[13] Thus, the impossibility of giving any safety assurance for thousands of chemicals that we know are widely used and hundreds that we know are released to the environment is a fundamental failure. It is a failure not of degree but of kind. This chapter explains how a key federal law has led to that failure.

More than 20 years ago, Congress recognized that lack of data was a potential Achilles' heel.

More than 20 years ago, Congress recognized that lack of data was a potential Achilles' heel for control and prevention of toxic chemical risks. In 1976, it declared:

> It is the policy of the United States that . . . adequate data should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such data should be the responsibility of those who manufacture and those who

process such chemical substances and mixtures.

15 U.S.C. § 2601(b).

"The development of data should be the responsibility of those who manufacture and process chemical substances"
15 U.S.C. § 2601(b)

The law that established this policy, and was intended to carry it out, was the Toxic Substances Control Act (TSCA), which created omnibus authority to require chemical testing and to impose controls as necessary.

Two decades later, this policy is largely defunct.[14] Chapter II has shown that even the first, minimal step of screening for toxicity has not been completed for most of the chemicals in the highest priority category, much less for commercial chemicals in general.

The primary cause of TSCA's failure, notwithstanding its clear policy goal, is its self-defeating legal structure,[15] discussed below. In addition, the Environmental Protection Agency in the past has been less than aggressive in seeking to carry out the law's provisions. A report from the General Accounting Office in 1984 concluded that EPA had been slow in implementing a chemical testing program under TSCA.[16] A followup report six years later found the same problem and noted the continuing absence of any "overall program objectives or strategy" on EPA's part.[17] In the last few years, EPA has begun to show significant improvement in comparison to previous years,[18] but not in comparison to the size of the task that faces it, and the agency's ability to improve is bound by the design of the statute itself. Yet as recently as 1996, the chemical manufacturing industry has reiterated its position that "[t]here are no fundamental flaws in TSCA" and that the law should not be revised.[19]

The Toxic Substances Control Act has several provisions that authorize EPA to compel production of data on potentially toxic chemicals. For chemicals already on the market, EPA may issue testing requirements to fill in the blanks when "there are

insufficient data and experience" to determine the effect of a chemical "on health or the environment"[20]; may direct chemical manufacturers to submit unpublished studies they know about; and may require chemical manufacturers and processors to provide certain basic information on request (e.g., fill out a two-page form on chemical quantities produced, use patterns, releases, and worker exposures).[21] Manufacturers and processors also have a duty to tell EPA if they have information "that supports the conclusion that [the chemical] presents a substantial risk of injury to health or the environment."[22]

In addition to these data-oriented provisions, TSCA also allows EPA to regulate chemicals directly. EPA may prevent "unreasonable risks" from toxic chemicals, by applying measures ranging from labeling up to and including a partial or complete ban on the chemical's sale.[23] Finally, for new chemicals not yet on the market, EPA reviews data that must be submitted 90 days before a new chemical is manufactured or processed. To fill data gaps, EPA may require additional testing before the chemical is allowed to be marketed, and EPA may limit production or use if the chemical poses an unreasonable risk.[24]

Together, these provisions of the Toxic Substances Control Act sound as though they would offer formidable protection against harm from toxic chemicals. It is worth a brief explanation to show why they work so poorly in practice, and why they were doomed from the start.

A. TSCA Section 4 — testing and review of existing chemicals

Section 4 of TSCA is the key testing section, the one most directly aimed at curing the problem of lack of testing data about chemicals in commercial use. In theory it authorizes the Environmental Protection

Agency to issue so-called test rules, to require testing and reporting of information about almost any chemical.[25]

Unfortunately, the actual provisions of Section 4 put EPA into a Catch-22: the agency must already *have* data in order to show that it *needs* data. It must do so not only chemical by chemical, but even test by test for each chemical. Even though a testing law is obviously supposed to combat ignorance about chemicals, this one is written so that ignorance about chemicals can keep it from working.[26]

Only five of the 71 sample chemicals lacking minimum safety screening data have been subjected to any TSCA Section 4 testing requirement.

Using all Section 4 measures combined, EPA has developed testing actions on only 263 chemicals in the past 20 years,[27] most of them recently.[28] Using as an example EDF's random sample of chemicals (discussed in Chapter II), only five of the 71 chemicals lacking minimum safety screening data have been subjected to any Section 4 testing requirement under TSCA. Of those five test rules, three fail to address major data gaps on specific human health impacts.[29] Even taking into account the recent upswing in activity to about 65 actions per year,[30] testing of existing chemicals under TSCA is making only a modest dent in the backlog of untested chemicals. EPA has now developed a Master Testing list that identifies the highest priorities for testing, which covers approximately 500 chemicals.[31]

B. TSCA Section 5 — screening new chemicals before they are manufactured

For new chemicals, as opposed to existing ones, Section 5 of TSCA appears to give the Environmental Protection Agency stronger tools. It allows EPA to pre-screen any new chemical before it is manufactured, and it requires a "pre-manufacture notification" (PMN) that must include certain information on the new chemical.

However, as with Section 4, the requirements of Section 5 were written in such a way that the law's theory can easily be defeated in practice. First and most obvious, under the regulations adopted to implement Section 5, **it is only optional and not mandatory for a pre-manufacture notice to include *any* actual data on a chemical's toxicity**.[32] Over half of pre-manufacture notifications are submitted with no toxicity data at all.[33] By contrast, European nations require a defined set of actual test results for new chemicals.[34]

In addition, the contents of a pre-manufacture notification are not binding, and thus there is no incentive for a manufacturer to insure that its original submission is accurate and reliable. Once the Environmental Protection Agency has reviewed a chemical based on its pre-manufacture notification, the manufacturer does not need to limit uses or production levels to those described in the notification.[35] Manufacturers can even change the contents of the document while it is being reviewed.

Within these severe restrictions, imposed by Congress in the structure of the Toxic Substances Control Act, EPA has tried to make the best of what little information on new chemicals that it does have the right to receive. In the absence of testing data, it has become a leader in the use of Structure-Activity Relationship (SAR) analysis, which tries to predict a chemical's likely toxicity based on its chemical structure. Limited experience to date suggests that the usefulness of SAR analysis varies considerably depending on the particular chemical characteristic sought to be predicted. One study, jointly sponsored by the U.S. Environmental Protection Agency and the European Community, showed very poor correlations between SAR predictions and actual test results for certain health effects and other chemical characteristics, relatively good correlation for at least

one health effect, and did not examine some other important health effects.[36]

Thus, the apparently comprehensive power under Section 5 for EPA (a) to obtain information on new chemicals before they are manufactured, and (b) to impose any needed controls on them as a condition of their being allowed to be manufactured, has been effectively given back to the manufacturers themselves. Conscientious manufacturers of new chemicals may submit full screening data in their pre-manufacture notifications, but they are currently not required to meet any minimum testing requirements similar to the requirements adopted by the OECD Chemicals Program.

C. TSCA Section 6 — catch-all authority for controls

In addition to testing and screening for existing and new chemicals, the Toxic Substances Control Act includes a section explicitly authorizing the Environmental Protection Agency to take action to control risks from toxic chemicals, ranging from labeling to outright ban. Section 6 allows EPA to proceed against any chemical that presents an "unreasonable risk of injury to health or the environment."[37]

In the law's 20-year history, regulatory actions under TSCA Section 6 have been taken against only five chemicals.

Nevertheless, the need to have enough information to show "unreasonable risk" has been enough to stymie EPA's use of Section 6 almost completely. In the law's 20-year history, regulatory actions under Section 6 have been taken against only five chemicals or chemical classes.[38] The chemical industry itself describes the number of Section 6 actions as "very few."[39] The way the law was written virtually guaranteed that it would be only rarely applied.

CHAPTER III NOTES

[12] See, e.g., the title of the *Safe* Drinking Water Act [emphasis added], 42 U.S.C. Sec. 300f *et seq*. (West 1991 & Supp. 1997). Different laws use different legal language to express the idea of safety. Most recently, in the Food Quality Protection Act of 1996, Congress defined it as a "reasonable certainty [of] no harm." 21 U.S.C. 346a, (b)(2)(A)(ii), amending Sec. 408(b)(2)(A)(ii) of the Federal Food, Drug, and Cosmetic Act. This definition clearly reflects that the goal is not perfect safety or total absence of any possible harm, but rather a high degree of reasonable assurance.

[13] See, e.g., the 1996 policy statement of the Chemical Manufacturers Association describing its view of chemical risk management: "Generally speaking, the philosophy of risk-based . . . management of chemicals . . . allows for the continued *safe* use of chemicals . . . . Through [this] approach, we can ensure that chemicals are used *safely*," [emphasis added]. Chemical Manufacturers Association, Overview, Product Risk Management Strategy (Arlington, VA: Chemical Manufacturers Association, 1996), p. 8. See also the same organization's much-publicized Responsible Care Program, required for all member companies, which commits members to "develop and produce chemicals that can be manufactured, transported, used and disposed of *safely*," and to "counsel customers on the *safe* use, transportation and disposal of chemical products" [emphasis added]. Chemical Manufacturers Association, 10 Elements of Responsible Care: 1994-95 Responsible Care Progress Report (1995), p. 2. The Chemical Industry Institute of Toxicology, a private research institution largely funded by industry, takes the position, "We all want a healthy society. . . . We want *safe* chemical products. On that we can all agree," [emphasis added]. Chemical Industry Institute of Technology, Annual Report 1995, Internet/WWW [address: http://www.ciit.org/AnnualReports/AR96.html].

[14] TSCA's failings have been repeatedly documented in both government and private reports. See GAO, Toxic Substances: EPA's Chemical Testing Program Has Not Resolved Safety Concerns (GAO/RCED-91-136, June 19, 1991); GAO, Toxic Substances: Status of EPA's Reviews of Chemicals Under the Chemical Testing Program (GAO/RCED-92-31FS, October 31, 1991); GAO, Toxic Substances Control Act: EPA's Limited Progress in Regulating Toxic Chemicals (GAO/T-RCED-94-212, May 17, 1994). See also following footnotes.

[15] See generally GAO, Toxic Substances Control Act: Legislative Changes Could Make the Act More Effective (GAO/RCED-94-103, September 1994). Throughout TSCA's history, chemical manufacturers have used the weaknesses of the law to sue EPA and delay its efforts to require chemical testing. Two appellate courts noted that EPA bears a higher burden of justifying regulatory action under TSCA than under the traditional "arbitrary and capricious" standard that applies to federal agency actions

generally. Shell Chemical v. EPA, 826 F.2d 295, 297 (5th Cir. 1987); Auismont U.S.A. Co. v. EPA, 838 F.2d 93, 96 (3rd Cir. 1988). See also Chemical Manufacturers Association v. EPA, 859 F.2d 977 (D.C. Cir. 1988).

[16] GAO, EPA's Efforts to Identify and Control Harmful Chemicals in Use (GAO/RCED-84-100, June 13, 1984).

[17] GAO, EPA's Chemical Testing Program Has Made Little Progress (GAO/RCED-90-112, April 25, 1990), p.3.

[18] See discussion below regarding test rules. In addition, during 1997, EPA is developing a specific Toxics Agenda to "systematically address[ ]" chemicals covered by TSCA. Presentation of William Sanders, Director, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, at TSCA 20th Anniversary Conference, November 12, 1996, Arlington, VA.

[19] Comments of Chemical Manufacturers Association on the Report of the Risk Assessment and Risk Management Commission, August 13, 1996, pp. 41-42: "CMA does not agree that Congress needs to rewrite or revise TSCA. TSCA is a risk-based statute and provides EPA with all of the authority and flexibility necessary for EPA to protect human health and the environment from unreasonable risks posed by new and existing chemicals."

[20] TSCA Section 4, 15 U.S.C. Section 2603 (West 1982), P.L. 94-469, 90 Stat. 2003.

[21] TSCA Section 8, 15 U.S.C. Section 2607 (West 1982).

[22] *Id*.

[23] TSCA Section 6, 15 U.S.C. Section 2605 (West 1982).

[24] TSCA Section 5, 15 U.S.C. Section 2604 (West 1982).

[25] TSCA's jurisdiction does not include some important categories of chemicals that Congress viewed as adequately addressed by other statutes, namely pesticides; tobacco products; certain nuclear materials; ammunition; and foods, food additives, cosmetics, drugs, and medical devices regulated by the Food and Drug Administration. TSCA Section 3(2)(B), 15 U.S.C. 2602(2)(B) (West 1982).

[26] Before EPA can issue a test rule (i.e., ask for testing) on a specific chemical, the agency must first show either (i) that the chemical may present an "unreasonable risk" or (ii) both that it is produced in major quantities and that either "substantial" exposures are occurring in quantitative terms (e.g., numbers of people exposed, or pounds being released) or that "significant" exposures are occurring in qualitative terms (a case-by-case

determination of the impact of exposures). Obviously, "substantial" exposures cannot be proven if quantitative information on releases of the chemical or exposures to the chemical is lacking. And "significant" exposures cannot be proven without information on the chemical's toxicity. When EPA does have a basis for worrying about a specific chemical's risk to health or the environment, but a factual question like the amount of exposure to that chemical remains in doubt, EPA can proceed only "where there is a more-than-theoretical basis for suspecting that some amount of exposure takes place and that the substance is sufficiently toxic at that level of exposure to present 'an unreasonable risk to health.'" Chemical Manufacturers Association v. EPA, 859 F.2d 977, 984 (D.C. Cir., 1988). In addition, before issuing a test rule, EPA must also show that existing data are insufficient, and that testing is "necessary." Industry can trip EPA in court on either of these hurdles as well.

[27] Environmental Protection Agency, Chemicals On Reporting Rules Database (CORR) (1996), Internet/WWW [address: http://www.epa.gov/docs/CORR].

[28] Presentation by Lynn R. Goldman, M.D., Assistant Administrator, EPA Office of Prevention, Pesticides, and Toxic Substances, "Successes and Lessons Learned During 20 Years of the Toxic Substances Control Act," p. 3. TSCA 20th Anniversary Conference, Arlington, VA, November 12, 1996. Dr. Goldman's talk indicates testing actions on 550 chemicals; the discrepancy with EPA's database (see previous footnote) is unclear.

[29] For example, EPA's test rule for 1,3-dichlorobenzene requests voluntary provision of biodegradation test results, but it does not address the complete lack of data on reproductive and developmental toxicity for 1,3-dichlorobenzene.

[30] Goldman, *supra* note 28.

[31] 61 Fed. Reg. 65936 (December 13, 1996).

[32] The U.S. Pre-Manufacture Notification (PMN) requires only the following information:

- the substance's chemical identity and structure, and impurities "anticipated to be present";
- byproducts from the manufacturing, processing, use, and disposal of the new substance;
- estimated maximum amount to be manufactured or imported during each of the first three years of production; and
- to the extent known, worker exposure and environmental release information, intended uses, and locations where the new substance will be handled.

40 CFR 720.45

[33] GAO 94-103, p. 34.

[34] Union Directive 79/831/EEC (1979, amending 67/548/EEC) requires any manufacturer or importer who markets more than one metric ton of a "new" substance to submit a notification dossier that includes results of the "Base Set" of tests, including physical and chemical properties; acute toxicity; sub-chronic toxicity (28-day study); mutagenicity; ecotoxicity; and environmental degradation. When the marketing levels for a substance exceed 10 metric tons annually, authorities may require additional data; at levels above 100 and 1000 metric tons annually, additional data requirements automatically apply (known as Level 1 and Level 2 testing packages). U.S. Environmental Protection Agency, Office of Pollution Prevention, Pesticides, and Toxic Substances, U.S. EPA/E.C. Joint Report on the Evaluation of (Quantitative) Structure Activity Relationships, Doc. No. EPA 743-94-001, Washington, D.C., 1994.

[35] GAO 94-103, *supra* note 15, p. 32. On occasion, when learning that EPA was considering controls on a chemical, manufacturers have reportedly gone back and lowered the exposure estimate for the chemical in the PMN to avoid EPA action. They have also revised PMNs to show lower releases than previously estimated, and added claims that the chemical will be used in a zero-release system. GAO 94-103, p. 37.

[36] U.S. EPA, Doc. No. EPA 743-94-001, *supra* note 34. As the report noted, "the project is not, and was not designed to be, an evaluation of [SAR] techniques in general." *Id.*, p. 3. Because the European Union's base data set does not include studies on most types of chronic toxicity, some critically important endpoints were not assessed at all.

[37] TSCA Section 6(a), 15 U.S.C. Section 2605(a) (West 1982).

[38] Final rules have been issued for: dioxin waste disposal; hexavalent chromium use in cooling towers; polychlorinated biphenyl manufacturer prohibitions (rule mandated by statute); metal fluids; and lead paint disclosures. In addition, two proposed rules have been issued: banning acrylamide grouts; and banning lead fishing sinkers.

[39] CMA, Overview, *supra* n. 13, at 3.

IV. Hints of Progress

The failure to obtain necessary minimum data on commercially important chemicals has been no secret to those directly involved. To try to fill in for the failures of regulatory government in this area, there have been various attempts to deal with the lack of data on chemicals through other means.

Voluntary efforts by the chemical industry to address the problem have generally been disappointing, at least to the extent of generating data that are publicly available.[40] The analysis in Chapter II above has covered virtually all reliable testing data that are available through public sources[41], whether voluntary or mandated, and it has shown how unsatisfactory the results have been.

However, one international effort has gone far toward recognizing and defining the problem of lack of preliminary screening data. At the same time, one federal law with a new approach has shown how to stimulate much faster progress than would seem possible from experience with the Toxic Substances Control Act.

A. The SIDS Program — Recognizing the Problem

In 1990, with extensive participation from industry, the Organisation for Economic Cooperation and Development took a major step by creating an international program to obtain basic information on high-volume chemicals.[42] The very name given to this

effort is itself a significant contribution. The Screening Information Data Set (SIDS) program emphasizes the idea of screening chemicals on the basis of a minimum or preliminary set of basic data about them (see accompanying chart). The OECD program helps to clarify and define the problem of lack of chemical information, and it undertakes to address the problem directly.

One important attribute of the OECD program is the sharing of the costs of testing among countries and among industries. Depending on how much testing had already been performed for a specific chemical, completing the screening information data set can cost between $20,000 to $150,000 per chemical, according to OECD estimates.[43]

OECD SCREENING INFORMATION DATA SET ELEMENTS[44]

1. General Information
   - Substance information
   - CAS-number
   - Name (OECD name)
   - CAS descriptor
   - Structural formula
   - Quantity (production ranges)
   - Use pattern (categories and types of use)
   - Sources of exposure

2. Physical-Chemical Data
   - Melting point
   - Boiling point
   - Relative density
   - Vapor pressure
   - Partition coefficient: n-Octanol/water
   - Water solubility
   - Dissociation constant
   - Oxidation-reduction potential

3. Environmental Fate and Pathways
   - Photodegradation (by estimation)
   - Stability in water (by estimation)
   - Monitoring data (environmental)
   - Transport and distribution between environmental compartments
   - Aerobic biodegradability

4. Ecotoxicological Data
   - Acute toxicity to fish
   - Acute toxicity to daphnids (chronic toxicity if there is concern for possible long-term effects)
   - Toxicity to algae
   - Appropriate terrestrial toxicity tests (if significant exposure is expected in the terrestrial environmental compartment or aquatic testing is not possible)

5. Toxicological Data
   - Acute toxicity
   - Repeated dose toxicity
   - Genetic toxicity (in vitro)
   - Genetic toxicity (in vivo)
   - Reproductive toxicity
   - Developmental toxicity/teratogenicity

Unfortunately, the program has been very slow in actually producing the information it seeks, as even some industry participants have noted.[45] To date, work has begun on 322 chemicals.[46] As of mid-1996, screening had been completed for 99 chemicals, with another 223 chemicals still in the pipeline at various stages.[47] Each year approximately 80 additional chemicals are added to the process. At the program's current pace, assessments of the currently targeted 2,500 chemicals would take another 25 to 30 years to complete, although some may be addressed by other international organizations.[48] Meanwhile, with the expansion of the global economy and with changes in materials production and use, the number of chemicals in the targeted category can be expected to grow.

At the current pace, SIDS assessments would take another 25 to 30 years to complete.

Of course, collecting the necessary screening data for hazard identification is only a first step. It provides enough preliminary data and toxicity test results to allow a reasonable judgment on whether further testing is needed. Some chemicals will require more extensive and detailed information to determine health hazards. For others, preliminary data may be enough to conclude that they probably pose minimal risk. However, under the OECD program, there is no international obligation on government or industry to take any action in response to the screening data, whether this involves more testing or reducing exposures. These activities are beyond the program's scope and are up to individual nations. As far as the OECD program is concerned, "[T]he overall responsibility for initiating and undertaking any [post-SIDS] work rests with industry."[49] There are no incentives or requirements[50] for doing so.[51]

B. The Toxics Release Inventory — Mandated Reporting and Public Disclosure

Eleven years ago, acknowledging the public's right to know about toxic chemicals, Congress required certain industrial facilities to report annually to the U.S. Environmental Protection Agency on the amounts of each of 329 specific chemicals that they release into the environment, creating what is known as the Toxics Release Inventory (TRI). The agency then makes that information available to the general public.[52] The listing criteria reflect some preliminary judgment as to a chemical's potential harm,[53] and the number of chemicals or chemical classes subject to the reporting requirements has since risen to 654.[54]

Getting this information and making it public has had a well-recognized effect. According to the Environmental Protection Agency, between 1988 and 1994, facilities covered by the law reduced their reported releases of chemicals on the TRI list by 44 percent, or 1.6 billion pounds.[55] Chemical company executives have acknowledged that the Toxics Release Inventory made them aware — in many instances for the first time — just how much pollution they were emitting and had a major impact in stimulating them to cut back on those emissions.[56]

The success of the Toxics Release Inventory comes purely from the power of information.

It is important to note, as many observers have, that the success of the Toxics Release Inventory comes purely from the power of information. Nothing in the law that created it imposed any new controls on chemicals. Companies acted to reduce their releases of chemicals after those releases were (or were about to be) announced to the public. The chemical manufacturing industry's reaction to the law has been erratic. Although its lead trade association publicly praises the law,[57] the same trade association recently sued to try to prevent the Environmental Protection

Agency from expanding the number of chemicals on the Toxics Release Inventory list.[58]

What the Toxics Release Inventory has accomplished is to show that disclosure can work as a strong incentive to improved industrial behavior with chemicals, even when information is lacking about the degree of hazard those chemicals may pose. TRI proved that a disclosure system by itself could offer important rewards for early, non-compulsory action, and that those rewards would work. By inviting public comparisons between individual companies, it can have the effect of stimulating competition among those companies for improvement.

Disclosure can work as a strong incentive to improve industrial behavior with chemicals, even when information is lacking.

However effective once mobilized, TRI's incentive depends on the existence of at least a partial preliminary hazard identification, for each chemical in question, sufficient to support its being placed on the TRI list. TRI does *not* address the problem of complete lack of hazard identification, as the OECD minimum screening information data set program does. For chemicals not included on the TRI list, there are no incentives or rewards for manufacturers to conduct tests or otherwise improve the knowledge base. But the incentive strategy embodied in TRI can also be used to stimulate hazard identification activity by spotlighting those chemicals for which data are lacking. The next chapter describes how.

CHAPTER IV NOTES

[40] There is, of course, no way to quantify the testing and other data on specific chemicals that may be in private hands.

[41] The methodology used to search publicly available databases, with the identity of the databases, is explained in Appendix I.

[42] Organisation for Economic Cooperation and Development Secretariat, SIDS Manual (Second Revision): Screening Information Data Set Manual of the OECD Programme on the Co-operative Investigation of High Production Volume Chemicals, (Paris, France: May 1996), Ch. 1, p. 3. OECD defines "High Production Volume" chemicals as those produced in quantities above 1,000 metric tons (2,200,000 lbs.) annually in each of any

two OECD member nations, or more than 10,000 metric tons (22,000,000 lbs.) annually in any one member nation. Currently, there are about 2,500 compounds on OECD's High Production Volume list, which was last updated in 1995.

[43] Turnheim, "Evaluating Chemical Risks," The OECD Observer, No. 189, August/September 1994, pp. 12-15.

[44] SIDS Manual, *supra* note 42, Ch. 2, pp. 2-3. Some elements of the box have been rephrased slightly for brevity. Exposure data are also requested as part of the minimum data set.

[45] Chemical Manufacturers Association, Environment, Health, Safety, and Operations Committee, Chemicals Testing Task Group, "The OECD Cooperative Investigation of High Production Volume Chemicals: Review of Program Status, 1996," (May 1997), p. 14 (noting that "a number of companies that have [participated in SIDS] . . . have expressed concern about the slow pace of movement through the SIDS process").

[46] Personal communication, Dian Turnheim, Principal Administrator, OECD Environmental Health and Safety Division, to Karen Florini, EDF, March 3, 1997.

[47] Testing is not conducted directly by the OECD; actual testing is carried out under the sponsorship of an OECD member nation, generally by a chemical manufacturer. Turnheim, *supra* note 44.

[48] SIDS dossiers on individual chemicals are provided to the International Program on Chemical Safety, a joint project of the United Nations Environment Program, the World Health Organization, and the International Labor Organization. IPCS in turn may use them in preparing Health and Safety Guides, or Environmental Health Criteria documents. SIDS Manual, *supra* note 42, Ch. 1, p. 9. However, there is no mechanism to enforce the guides or the criteria documents, unless and until they are used as the basis for regulatory action by individual governments.

[49] SIDS Manual, *supra* note 42, Ch. 1, p. 8.

[50] See discussion *supra* note 48.

[51] The OECD has recently established an Advisory Group on Risk Management that is charged with "accelerating priority risk reduction," but no specific measures have been adopted as of July 1997.

[52] Emergency Planning and Community Right-to-Know Act of 1986, 42 U.S.C. Sec. 11001-11050 (West 1995), P.L. 99-479, 100 Stat. 1613.

[53] The 329 chemicals which Congress placed on the TRI list at the outset came from preexisting lists developed by the States of Maryland and New Jersey. EPA was authorized to delete

chemicals which turn out not to meet the law's specified criteria for listing, as well as to add chemicals which do. A chemical may be listed if it is known or anticipated to cause significant acute effects beyond the facility boundary; to cause chronic effects such as cancer, neurological disorders, or other chronic effects; or to cause adverse effects on the environment.

[54] 40 CFR 372.65. In addition to manufacturing facilities covered by the program to date, seven additional industry sectors will also have to report, beginning in 1997, under a final rule announced by President Clinton on April 22, 1997 (Earth Day).

[55] 61 Fed. Reg. 51322 (Oct. 1, 1996). Because of concerns about the accuracy of reports filed in the program's first year (1987), EPA generally uses the year 1988 as the baseline. Between 1987 and 1992, production of basic industrial chemicals increased by 18%. Chemical Manufacturers Association, "Responsible Care Communication," March 10, 1995, Internet/WWW [address: http://es.inel.gov/techinfo/facts/cma/cmacommo.html].

[56] Examples:

- "In the long history of legislation in the United States, passage of Title III in 1986 was the most important for Monsanto Company." — Earl Beaver, Monsanto; Proceedings, International Conference on Reporting Releases of Toxic Chemicals, November, 1991.
- "[The first TRI data] shocked a lot of the industry folks, the magnitude of these releases. It really hit home. People from boardrooms all the way down to plants recognized they had to get aggressive to try to find ways to reduce these emissions." — Dan Borne, Louisiana Chemical Association; The Times-Picayune, February 17, 1991.
- "[TRI] really forced us to look at the numbers in a condensed way, and it dawned on us that these were some big numbers. Maybe it's just a big number, but people don't like that." — Randy Emery, Amoco; Houston Chronicle, July 24, 1989.
- "It's not necessarily that we didn't want to [reduce emissions] before. We never had the information we needed to know if progress was being made." — Steven Schoger, BP Chemicals (Cleveland, Ohio); Occupational Hazards, July 1991.

See generally Working Group on Community Right-to-Know, "What Industry Has Said About TRI," July 1995.

[57] "We continue to believe that T.R.I. has been a very successful venture. Our members have gotten behind it and witnessed a 50 percent reduction in pollution." — Mort Mullins, Chemical Manufacturers Association; quoted in The New York Times, June 28, 1995.

[58] National Oilseed Processors Association, Chemical Manufacturers Association, et al., v. EPA, 924 F. Supp. 1193 (D.D.C. 1996), appeal docketed *sub nom*. Troy Corporation, et al. v. Browner, No. 96-5188 (D.C. Cir. 1996). The trial court in the case concluded that "EPA went to great lengths to separately evaluate each and every chemical on the basis of the relevant data," 924 F. Supp. at 1217.

V. Recommendations

In a world of chemicals, the most basic policy question is what to do in the face of lack of information.

The steps that are suggested in this chapter are intended to shift incentives away from the status quo, in order to begin to discourage commercial use of massive quantities of chemicals that have not at least been screened for basic toxicity. To be effective, incentives should stimulate both (a) the gathering and disclosure of screening information about major chemicals and (b) early actions to reduce the use of and prevent exposures to chemicals that have been identified as hazardous or that have not been screened.

The most basic policy question is what to do in the face of lack of information.

Considering incentives does not mean ignoring or abandoning direct requirements on manufacturers to test their chemicals. The 20-year failure of the Toxic Substances Control Act does not mean that testing requirements are necessarily futile; it means only that, to work, they need to be much better designed. Merely adding agency staff and laboratory resources or enforcement authority to existing TSCA requirements will *not* significantly improve performance in getting the necessary tests performed and the necessary information to the public. The law itself will have to be rewritten to get the necessary design changes.

A. A right to know what we *don't* know

Thanks to the Toxics Release Inventory, members of the public now have the right to know about some potential sources of exposure to a few hundred chemicals with partially known risks. It is a right they appreciate and have come to expect. In just the same way, they should have the right to know about possible sources of exposure to important chemicals that have *unknown* risks.

Labeling ignorance as ignorance, rather than safety, is an important first step.

1. Disclose the status of knowledge about individual chemicals

Labeling ignorance as ignorance, rather than safety, is an important first step. Either government or private parties can publicize the state of scientific knowledge (and ignorance) about individual chemicals. Much specific information, or the fact that such information is absent, can now be compiled on a chemical-by-chemical basis; the database described in Appendix I and used in this report is an example. With modest additional resources, such databases can be made readily searchable by any member of the public and can be made available to the public on the Internet. This information can and should become a basic element of right-to-know policy about chemicals in substantial circulation in commerce.

2. Define the criteria for minimum necessary screening information

Apart from creating effective public access to what is and is not already known, government can take an important definitional step. Using current science, it can determine what constitutes a minimum necessary set of scientific data for a given chemical that makes it possible to screen that chemical for safety, on a preliminary basis.

The advantage of a clear definition is simplicity. A chemical either would, or would not, meet the defined criteria for minimum screening information.

Once determined, this kind of status is easy to communicate to a wide audience.

The OECD minimum screening information data set, discussed above in Chapter IV, is one example of such a definition. The OECD criteria can be used immediately as an interim definition, to be replaced when U.S. EPA or another designated independent agency completes its own. An existing definition that takes effect in the interim is critical, in order to act as a disincentive to prolonged delay.

It is important to use criteria that are appropriate for early screening, as OECD has done, rather than making the criteria so comprehensive that meeting them in the near future is not feasible. It is equally critical that the definition be able to be updated easily whenever there are significant advances in scientific techniques or awareness of hazards (e.g., the emerging problem of environmental endocrine disruptors). For example, it has been predicted that advances in molecular toxicology will make animal testing and other current screening methods obsolete.[59] If so, a definition that required specific tests as screening requirements would need to be promptly revised.

3. Identify Toxics Release Inventory chemicals that have not been screened for safety

If any chemical on the Toxics Release Inventory does not have available the minimum information necessary for health safety screening, the public's right to know should include that fact as part of all reports of the chemical's release. This would accurately convey to the public the unknown nature of the risk represented by releases of such a chemical. It would also create a useful incentive for manufacturers or users of TRI-listed chemicals to acquire the necessary data to avoid such a designation.[60]

4. Report on releases of unscreened chemicals — an "Unknowns Release Inventory" (URI)

A reporting system parallel to the Toxics Release Inventory should be established for releases of major chemicals that do *not* have available the minimum information necessary for safety screening. Such an Unknowns Release Inventory, a "URI," would give force and effect to the public's right to know about all major *unscreened* chemicals to which the public is being exposed. The number of chemicals involved would depend on how quickly the manufacturers or releasers of the chemicals in question choose to generate and disclose the necessary data.

An Unknowns Release Inventory would give force and effect to the public's right to know about all major unscreened chemicals to which the public is being exposed.

This step should take effect only after a reasonable grace period expires, in order to give responsible industries a reasonable time to produce the necessary data and thus avoid URI listing for their chemicals by demonstrating — through screening data — that the chemicals pose low enough risks that reports are unnecessary. Avoiding URI reporting requirements would presumably be a substantial incentive for a chemical's manufacturer or user to produce the data. For those that choose not to, the public will at least have useful information on the location and quantity of some of the major industrial sources of the chemicals in question.

The coverage of a URI should also be phased in over time, beginning with chemicals in the largest-volume category (e.g., over 1,000,000 lbs./yr.) and eventually reaching all chemicals within the TRI "high volume" category (e.g., over 10,000/lbs.yr.). An appropriate phase-in, with three steps, might provide a one- or two-year grace period for chemicals in the 1,000,000 lbs./yr. category; another two years for chemicals between 100,000 lbs./yr. and 1,000,000 lbs./yr.; and additional years for chemicals between 10,000 lbs./yr. and 100,000 lbs./yr.

Other chemicals of special importance — for example, those with high worker exposure or particular health or environmental dangers identified in the course of existing regulatory programs — could also be placed in Phase I, II, or III, independent of volume criteria. For example, for a hazardous air pollutant already identified by Congress but not yet screenable due to lack of testing data, it would make no sense to wait several additional years before adding it to a URI list simply because its total production volume is less than 1,000,000 lbs./yr.

A URI should also have an automatic exclusion for one set of chemicals that, as a class, is very unlikely to present health hazards — i.e., high-molecular-weight polymers — and authority for EPA to exclude other individual chemicals or chemical classes on similar grounds after a sufficient scientific showing as defined in the law.

B. Alterations in legal status for chemicals that cannot be screened for safety

Chemicals in substantial commercial use in the U.S. hold legal status and thereby enjoy certain legal privileges, some more widely recognized than others. Their status and their privileges depend, in large part, on an assumption that the chemicals are not posing unacceptable harms to human health or to the environment. If they were, then the regulatory system should — in theory — have already banned or restricted their use. As this report documents, this presumption of safety is most often based on ignorance rather than on any reliable scientific information.

A failure to provide test results should cause progressive withdrawal of legal privileges over time.

Once it is recognized that a chemical's status and privileges depend on a presumption of safety, it is obvious that a failure to justify that presumption should result in progressive withdrawal of legal

privileges over time. The examples below are illustrative rather than comprehensive.

1. Lower the threshold for TSCA testing

As discussed in Chapter III, Section 4 of the Toxic Substances Control Act requires the Environmental Protection Agency to have substantial data in hand before it can require testing on existing chemicals. If a high-production-volume chemical cannot meet minimum screening data requirements after a defined grace period expires, the burden should be reversed: testing should automatically be required unless EPA affirmatively determines that it is not needed. In other words, ignorance should make a chemical *more* of a priority for government-imposed testing obligations, not less.

2. Reclassify as "new" chemical under Toxic Substances Control Act

If a chemical in current or long-standing use continues without meeting minimum screening data requirements for a substantial period of time, i.e., after a multi-year grace period expires, there is no logical reason that it should enjoy grandfathered status under the law. As an unknown risk, it becomes much more akin to a "new" chemical than an "old" one. Under the Toxic Substances Control Act, it would therefore be appropriate for such chemicals to be automatically reclassified as "new" chemicals for purposes of Section 5. In other words, such chemicals would forfeit their "grandfather" privileges. The mechanics of Section 5 would need to be slightly adjusted to accommodate this reclassification.

Untested chemicals would forfeit their "grandfather" privileges.

3. Invalidate trade-secret claims

Current law offers protection of some information on chemicals that manufacturers, importers, or users deem confidential. Once again, if a high-production-volume chemical persists in commercial use for a substantial period of time without being able to meet

minimum data requirements, the rationale for allowing protection of confidential business information is seriously weakened. The price of maintaining trade secrets about a chemical should be public disclosure of at least the minimum scientific information necessary for safety screening. Thus, after an appropriate time interval, trade-secret protection should be invalidated as a matter of law for any information about a high-production-volume chemical that has not met the minimum screening data requirements. The invalidation should apply in all legal contexts, not just TSCA or TRI.[61]

After an appropriate time interval, trade-secret protection should be invalidated as a matter of law.

4. Add lower-production-volume chemicals over time

Alterations of legal status can be phased in over time for other categories of chemicals as well, such as lower-production-volume chemicals or other priority classes of chemicals.

Each of the four steps discussed above is relatively easy to implement and relatively inexpensive. For government, the burden consists primarily of additional data management, which would be difficult only if the minor funding required were unavailable. A decade's experience with TRI data management provides a basis for confidence that the tasks are manageable.

For private business, the maximum cost for each chemical is the cost of generating and making available a defined set of necessary safety screening data, estimated (in the context of the OECD minimum screening information data set) as approximately $20,000 to $150,000.[62] For a chemical being sold in quantities exceeding 1,000,000 lbs./year, this should be a very modest cost in comparison to revenues. The cost of making disclosures for the same chemical would presumably be even less, since otherwise, the manufacturer or other responsible entity would pay to test.

Moreover, the testing and disclosure costs for a chemical need to be incurred only once. They do not fall on every business responsible for a chemical, or even on every manufacturer of the chemical. It is reasonable to expect that the largest producers or users will shoulder those costs jointly.

C. More effective mandatory testing for both new and existing chemicals

Although perhaps politically difficult, it would be conceptually easy to strengthen the testing authority of the Toxic Substances Control Act for both new and existing chemicals. Congress could easily direct industry to develop basic data (e.g., such as that required by the OECD Screening Information Data Set) for new and existing chemicals, using a phased timetable for existing chemicals and for new chemicals as they are developed. A key element for success — one that is currently missing — would be an automatic sanction for failure to produce timely data. This sanction must *not* depend on agency initiative before it is invoked. For example, the law could provide that no chemical in a specified class which does not have specified data publicly available by a fixed deadline may be released; or be the subject of a permit; or be manufactured; or be sold; etc.

As with the URI proposal discussed above, such a mandate could include both automatic and discretionary exclusions for individual chemicals or classes of chemicals where the information is demonstrably not needed to assure safety.

CHAPTER V NOTES

[59] Farr, "Molecular Assays for Environmental Endpoints," Screening and Testing Chemicals in Commerce, U.S. Congress, Office of Technology Assessment (Washington, D.C.: 1995), pp. 79-84. Doc. No. OTA-BP-ENV-166.

[60] At first thought it might seem that TRI-listed chemicals must already have sufficient minimum data available, since evidence of some form of risk was necessary to get them listed in the first place. However, few TRI-listed chemicals have actually been studied beyond the feature that cause them to be included on the list. A known carcinogen, for example, may never have been studied for its effects on reproduction, or on the environment.

[61] At present, confidentiality claims under the Toxic Substances Control Act continue in perpetuity, regardless of whether a chemical is on the market. TSCA Sec. 14, 15 U.S.C. 2013 (West 1982). Among other problems, this "limit[s] the ability of outside parties to independently scrutinize, validate, and improve upon EPA [Structure-Activity Relationship] models," because a significant portion of the underlying data have been claimed as confidential. Ann M. Richard, Pauline Wagner, Richard Purdy, and Gilman Veith, "SAR and Modeling," Screening and Testing Chemicals in Commerce, Doc. No. OTA-BP-ENV-166, U.S. Congress, Office of Technology Assessment (Washington, D.C.: 1995), pp. 101-115.

[62] Turnheim, "Evaluating Chemical Risks," The OECD Observer, No. 189, August/September 1994, pp. 12-15.

Conclusion

Taken together, the measures recommended above are relatively easy to implement and inexpensive for all parties to comply with. They could go far toward reducing our current massive ignorance about the basic toxicity of the major chemicals in U.S. commerce.

These measures are only the beginning of a solution to the problem documented in this report. Once necessary screening data are available (or once the use of major chemicals lacking such data is being seriously reduced), then the chemicals in question must actually be evaluated, and regulators must take the appropriate actions in response to screening results. Further testing and data gathering in some cases will be required. Control actions in some cases will be essential. The job of assuring public safety from chemicals is not over until all of these tasks are completed, for all chemicals that potentially pose a risk.

Fortunately, experience suggests that as information becomes more available, responsible industry can and does practice a greater and greater degree of self-control. Public knowledge is a powerful motivator. Once there is an expectation that the public will learn about potentially unsettling information (including *both* risks *and* uncertainties), companies have shown a desire to act in advance to minimize the unsettling elements and to reduce uncertainties. The system becomes self-enforcing rather than self-defeating. That is the direction we must take.

The system can become self-enforcing rather than self-defeating.

Appendix I. Data Sources and Methods

This appendix presents the data sources and methods used by EDF in this report to evaluate whether the preliminary screening data needed to assess the human health impacts of a given chemical are available. Part A describes EDF's database of chemical information and defines how the chemicals that are analyzed in this report were selected. Part B explains the analytical methods EDF used to make the major findings of the report. Part C describes how EDF identified chemicals known to be released to the environment or expected to have significant exposure potential.

A. Selection of chemicals analyzed in this report

U. S. EPA currently estimates that there are over 75,000 chemicals in commercial use.[1] A detailed evaluation of the availability of environmental information for chemicals is feasible only if it focuses on smaller categories of chemicals of concern. EDF selected the chemicals it evaluated in this report from the universe of substances included in a database of chemical information that EDF has created as part of a public information effort. This database includes all chemicals that are produced or imported in high volume and all chemicals that are the subject of regulatory attention under major U.S. or California environmental statutes.

U.S. EPA defines "high production volume" (HPV) chemicals as substances with annual import or production exceeding one million pounds. These chemicals can be feedstock or intermediates in manufacturing processes (e.g., hydrofluoric acid), constituents of consumer products (e.g., octane), or products in their own right (e.g., kerosene). EPA's 1990 list of HPV chemicals includes 2,971 compounds.[2] To identify chemicals that are the subject of regulatory attention, EDF included all chemicals regulated under any of the following federal and state environmental statutes:[3]

Federal

- Clean Air Act;
- Clean Water Act;
- Comprehensive Emergency Response, Compensation and Liability Act (Superfund);
- Emergency Planning and Community Right to Know Act (TRI);
- Federal Insecticide, Fungicide and Rodenticide Act;
- Occupational Safety and Health Act; and
- Safe Drinking Water Act.

California

- Air Toxics "Hot Spots" Information and Assessment Act;
- California Occupational Safety and Health Act;
- California Safe Drinking Water Act; and
- Safe Drinking Water and Toxic Enforcement Act (Proposition 65).

This report focuses on a random sample drawn from what are described in the text as **high-priority chemicals**. High-priority chemicals are defined as substances that are *both* used in high volume *and* are subject to current regulatory attention. EDF merged various lists of chemicals subject to state and federal regulatory attention with EPA's list of high-production-volume chemicals and identified 486 chemicals as high-priority chemicals. Priority consideration is justified for such chemicals because they are used in substantial quantities (increasing the likelihood of environmental release and exposure) and because they have been identified as a potential hazard by at least one regulatory program.

EDF randomly selected 100 chemicals from this set of high priority chemicals for its analysis of the availability of basic hazard identification data. This sample is statistically representative of chemicals in wide commercial use that have come to regulatory attention.[4]

B. Methodology for assessing availability of basic hazard identification data for high-priority chemicals

1. Adopting an internationally accepted minimum data set for identifying human health hazards

To evaluate the extent of hazard identification data available on each randomly selected high priority chemical, EDF relied on an internationally accepted definition of the minimum data set required for hazard identification. The Organisation for Economic Cooperation and

Development has defined the minimum data elements that are required to make a preliminary informed judgment regarding a range of potential hazards of chemicals, including but not limited to human health effects. The elements of this Screening Information Data Set[5] (SIDS) are shown in Chapter IV of the report. The human health component of this minimum screening data set includes toxicity test results in each of six broad categories of adverse health impacts:

- acute toxicity;
- repeated dose toxicity;
- *in vitro* genetic toxicity;
- *in vivo* genetic toxicity;
- toxicity to reproduction; and
- developmental toxicity (including teratogenicity).

For each chemical in the random sample, EDF examined whether any data are publicly available on each of these six essential elements of a minimum human health data set. It is important to note that chemicals found to possess these six data elements may still lack other essential data on environmental fate or ecotoxicity which are required to meet the requirements of the OECD program's minimum data set. A comprehensive approach to hazard identification would examine not only health effects but also the fate of a chemical in the environment and whether the chemical poses potential harm to ecosystems. For this report, EDF focuses only on the minimum data required to screen a chemical for its potential hazard to human health.[6]

2. Searching and scoring available toxicity data

To assess whether the defined minimum set of data exists, in public form, for each of the 100 chemicals in the random sample, EDF searched four major electronic databases for toxicity data relevant to human health impacts:

- the Registry of Toxic Effects of Chemical Substances (RTECS);[7]
- the Hazardous Substances Data Bank (HSDB);[8]
- Toxline;[9] and
- Medline/Medlars.[10]

The HSDB was also used to identify the major producers of chemicals in the random sample.[11] EDF identified several additional sources of toxicity data that it considered for inclusion in this analysis but rejected because of database quality or access problems.[12] The results of these searches were compiled in a Microsoft Access database for analysis.

In each of the six areas of human heath effects covered by the OECD program's defined minimum data set, any one of a variety of specific toxicity tests could provide the needed information. EDF identified 72 specific toxicity tests which are generally used to assess human health impacts and which might be conducted to meet the defined requirements.[13] The "Toxicity Data Availability Scoring Sheet" shown in Appendix II identifies the specific toxicity tests that might satisfy each broad category in the screening information data set. For example, there are nine specific toxicity tests that are frequently used to assess a compound's acute toxicity (involving different test species, routes of exposure, etc.).

EDF analyzed the publicly available toxicity data on each chemical in the random sample to determine which of the 72 types of toxicity tests had reported for that chemical, and then ascertained whether at least one qualifying test had been done in each of the six defined categories. If a chemical's data set included results for any one of the specific tests within a given category, it was considered to have satisfied the screening information requirement for that category. Chemicals with at least one test in all six health categories were considered to have a complete minimum screening information data set. Chemicals without test results in one or more of the six categories were considered to lack a minimum data set.

This scoring method probably overstates the availability of data from well-conducted toxicity tests. If the data sources indicated that a relevant study had been conducted, it was scored as sufficient. EDF did not review specific studies to determine whether they comply with OECD or EPA guidelines for conducting specific tests. The National Research Council's detailed evaluation of toxicity testing in 1984 found that only one-quarter of published toxicity tests met the standards of reference protocol guidelines or were judged adequate by expert committees.[14] EDF's analysis is therefore likely to overstate the number of chemicals for which minimum health hazard screening data are available.

C. Identifying high-priority chemicals that are known to be released to the environment or are expected to have significant potential for human exposure

To identify whether people are likely to come into contact with the chemicals in its random sample of high-priority chemicals, EDF ascertained which chemicals in the sample are known to be released to the environment or are expected to have significant potential for human exposure.

Chemicals were considered "known to be released to the environment" if reports to the 1995 Toxic Release Inventory (TRI) indicate they were released to air, water, or land.[15] TRI's reporting requirements were established by the Emergency Planning and Community Right-to-Know Act of 1986. However, reported releases under TRI are likely to be a substantial

underestimate of total environmental releases, because the requirements apply only to certain manufacturing facilities.[16] It is inappropriate to conclude that the absence of TRI data means that a chemical is not released to the environment.

Chemicals were considered to have a significant potential for human exposure if they scored "medium" to "high" in human exposure potential according to EPA's Waste Minimization Prioritization Tool.[17] This tool ranks over 800 chemicals by their human exposure potential, based on each chemical's persistence in the environment and its tendency to bioaccumulate. If a chemical persists in the environment (because it is resistant to biodegradation or other destruction pathways), its long-term human exposure potential is increased. If a chemical bioaccumulates in the environment (increasing in concentration as it moves up food chains), there is increased exposure potential for humans via food pathways.

APPENDIX I NOTES

[1] As of October 1996, there were 75,857 chemicals in EPA's TSCA Inventory.

[2] EPA's list of High Production Volume (HPV) chemicals can be obtained as digital media from the agency's Office of Prevention, Pesticides, and Toxic Substances. Pesticides and food additives are excluded from listing as high-production-volume chemicals because of provisions in the Toxic Substances Control Act. Some chemicals are included in more than one of these categories.

[3] Most regulatory lists utilized by EDF are included on a chemical cross-index compiled by CalEPA (1996) entitled "List of Lists," which can be obtained from the Hazardous Materials Data Management Program, Department of Toxic Substances Control, CalEPA, Sacramento, CA, Internet/WWW [address: http://www.calepa/cahwnet.gov/cci.htm]. Additional regulatory lists were obtained directly from the Code of Federal Regulations, as summarized in the Book of Lists for Regulated Hazardous Substances, published in CD-ROM format by Government Institutes, Inc., Rockville, MD.

[4] The manufacturers of high production volume chemicals included in EDF's random sample can be identified using data from the Hazardous Substances Data Bank and SRI International's Directory of Chemical Producers. SRI International, Directory of Chemical Producers: United States of America, (Menlo Park, CA: Chemical Industries Division, SRI International, 1996).

[5] The Screening Information Data Set is based on characterization and effects elements similar to those found in the Minimum Premarketing set of Data (MPD) adopted by OECD in 1982. The MPD was designed for the purposes of making an initial assessment of the hazards of newly marketed chemicals. Turnheim, "Evaluating Chemical Risks," The OECD Observer, No. 189, August/September 1994.

[6] This focus on the availability of human health data was necessary because of resource constraints: evaluating the availability of the minimum data required to identify hazards based on environmental fate, ecotoxicity or use, release, and exposure would have tripled the research required to produce this report.

[7] The Registry of Toxic Effects of Chemical Substances (RTECS) is a non-bibliographic database of toxicological information on some 130,000 chemicals maintained by the National Institute for Occupational Safety and Health (NIOSH). In addition to regulatory standards and updates on governmental agency activities, RTECS contains

information on six main toxicity areas: primary irritation, mutagenic effects, reproductive effects, tumorigenic effects, acute toxicity, and other multiple dose toxicity.

RTECS records the quantitative findings of toxicity tests (e.g., LD_{50}s) with references, drawing its data from a core set of about 200 technical journals, as well as abstracts, government reports, textbooks, proceedings of scientific meetings, compendia, industry reports and letters, professional society reports, reports by research institutions, personal communications, and publications from a large number of non-English language journals.

EDF retrieved all data indexed under the six main toxicity areas from a version of RTECS that was current through April 1996, contained on a CHEM-BANK CD-ROM at the University of California at Berkeley Public Health Library. RTECS had records for all 100 chemicals in the random sample.

[8] The Hazardous Substances Data Bank is a non-bibliographic, peer-reviewed database, created and maintained by the National Library of Medicine (NLM) and containing information on some 4,500 potentially hazardous chemicals. Focusing primarily on chemical toxicology, HSDB is further enhanced with data from such related areas as emergency handling procedures, environmental fate, human exposure, detection methods, and regulatory requirements. Data are derived from a core set of standard texts and monographs, government documents, technical reports, and the primary journal literature.

EDF retrieved entire chemical records from a version of HSDB that was current through April 1996, contained on a CHEM-BANK CD-ROM at the University of California at Berkeley Public Health Library. HSDB had records for 95 chemicals in the random sample.

[9] TOXLINE is a bibliographic, on-line database, maintained by the NLM and covering toxicological, pharmacological, biochemical, and physiological effects of drugs and other chemicals. Approximately 75% of the articles have English abstracts. TOXLINE takes its information from 18 secondary database sources: Aneuploidy, Chemical-Biological Activities, Developmental and Reproductive Toxicology (DART), Environmental Mutagen Information Center File (EMIC), Environmental Teratology Information Center File, Epidemiology Information System, Federal Research in Progress , Hazardous Materials Technical Center, International Labour Office (CIS), International Pharmaceutical Abstracts, NIOSHTIC, Pesticides Abstracts, Poisonous Plants Bibliography, Toxic Substances Control Act Test Submissions (TSCATS), Toxicity Bibliography, Toxicological Aspects of Environmental Health (BIOSIS), National Technical Information Service Toxicology Document and Data Depository, and Toxicology Research Projects (CRISP).

TOXLINE provides access to several important data sources that are not covered by the preceding databases. DART and EMIC cover reproductive and developmental studies which the other databases may slight. In addition, TSCATS contains summaries of the data being generated in response to TSCA toxicity testing and reporting rules that are conducted by private firms and rarely published in the scientific literature. TOXLINE also contains summaries of regulatory agency chemical assessments (e.g., by EPA or WHO) with extensive abstracts describing toxicity data available for a specific chemical. Toxicity tests summarized in these summary secondary sources were also included in EDF's scoring.

EDF obtained a MEDLARS account and accessed TOXLINE using the GRATEFUL MED software package. Because of the variety of secondary sources, keyword (KW) searches are highly unreliable. Both UC Berkeley reference librarians and the NLM suggest searching TOXLINE using the text word index, TW. Using GRATEFUL MED's Medical Subject Heading (MeSH) Thesaurus, keywords which GRATEFUL MED interprets as TWs were selected. The standard search was for CAS number and TW "*toxicity tests"* or "*pharmacokinetics"* or "*reproduction"* or "*growth and development";* was limited to English entries; excluded Medline references; and retrieved abstracts if available. The search routine was applied to TOXLINE's current on-line database, covering 1981-present, and produced records for 93 chemicals.

[10] MEDLINE is a bibliographic database, maintained by the NLM. MEDLINE contains articles from some 3,700 international biomedical journals, covering the fields of medicine, nursing, dentistry, veterinary medicine, and the preclinical sciences. Approximately 75% of the articles have English abstracts.
With the assistance of UC Berkeley research librarians, EDF created a template for conducting a keyword (KW) search of this database. The standard search was for CAS number and KW toxic# or adverse or pharma#; was limited to English entries; and retrieved abstracts if available. (Using the # sign after "toxic" searches for the letter string "toxic" in any word or phrase.) Note that the key words did not include terms such as carcinogen, mutagen,

or teratogen in order to avoid introducing too much specificity into the search. The KW search in MEDLINE not only searches article titles and abstracts, but also subject headings. Particular toxicities (such as teratogenicity) fall within the general subject headings of toxicology, adverse effects, etc.

The search routine was applied to MEDLINE's current on-line database, covering 1992-present, and produced records for 74 chemicals. Searching the MEDLINE database for records prior to 1992 would have required repeating the entire search effort, as the database is broken into several covered time periods. The marginal gain in coverage from searching earlier database periods was judged to be small, as substantially more toxicity data over longer time periods were available through RTECS and HSDB.

[11] HSDB identifies the major producers of a chemical (including parent company and production site locations). Because HSDB incorporates data from a variety of sources that can become outdated (e.g., as companies merge or change their product line), EDF verified that companies were recorded as producers of a random sample chemical in SRI's 1996 survey of chemical producers. See note 4 *supra*.

[12] The most significant of these potential sources was EPA's TSCA Triage Database, available in electronic form from EPA's Office of Prevention, Pesticides and Toxic Substances. U.S. EPA, Office of Prevention, Pesticides and Toxic Substances, TSCA 8(e) Triage Database, version 2.0 of 8(e), (Washington, D.C.: U.S. EPA, 1996), Internet/WWW [address: http://www.epa.gov/docs/8e_triage/]. TSCA Section 8(e) requires industry to report "substantial risk" information to EPA, excluding studies published in the open scientific literature or studies already reported to EPA as a result of other regulatory requirements. Since 1977, over 10,000 notices covering a wide range of chemical substances and mixtures and a variety of toxic effects and exposures have been submitted to EPA. Unfortunately, the Triage Database has substantial design and quality problems: chemicals are frequently identified with incorrect CAS numbers; study records are often inadequate to assess what type of test is being reported; many studies involve mixtures and not distinct chemicals; and cross-referencing within database files do not retain referential integrity. EDF was able to ascertain that including toxicity test reports in the Triage database in its assessment of toxicity data availability does not change the number of compounds that lack minimum datasets. It was not possible to include the Triage database results in our scoring of the availability of the 72 tests included in our comprehensive human health data set.

EDF also evaluated several electronic compilations of Manufacturer's Safety Data Sheets as a source of toxicity data. An MSDS summarizes available health and safety data on a chemical and must be provided by chemical producers and marketers to end users to comply with OSHA's Hazard Communication Standard. Unfortunately, substantial data quality and public access problems convinced EDF that these documents are not a useful source for evaluating data availability. Different manufacturers produce a different MSDS for the same chemical, with inconsistent descriptions of toxicity data and without citation to original data sources. Moreover, only some manufacturers allow MSDSs to be included in publicly accessible databases. The Chemical Manufacturers Association's CHEMTREC database, for example, allows only emergency response services to access all of its MSDS files. Some companies registered with CHEMTREC allow public access to their MSDS files on a non-emergency basis (although they charge a fee for providing the MSDS).

[13] These tests comprise all toxicity tests with official OECD (1996) guidelines or EPA (1996) guidelines. Organisation for Economic Cooperation and Development Secretariat, SIDS Manual (Second Revision): Screening Information Data Set Manual of the OECD Programme on the Co-operative Investigation of High Production Volume Chemicals, (Paris, France: May 1996). U.S. EPA, Office of Prevention, Pesticides and Toxic Substances, OPPTS Test Guidelines: Series 870, Health Effects, Volume I (Washington, D.C.: U.S. EPA, 1996), Internet/WWW [address: http://www.epa.gov/docs/OPPTS_Harmonized/]. They also include additional tests identified in the National Research Council's 1984 report on toxicity testing as components of a comprehensive human health data set. National Research Council, Toxicity Testing (Washington, D.C.: National Academy Press, 1984).

In order not to exclude potential toxicity information, the following test types were expanded to include virtually any relevant study: reproduction and fertility effects, preliminary developmental toxicity screen, prenatal developmental toxicity study/teratology study, neurotoxicity screening battery, metabolism and pharmacokinetics.

[14] *Id.*

[15] EDF used 1995 TRI data, the latest available, obtained from EPA's TRI web site in June 1997, Internet/WWW [address: http://www.epa.gov/opptintr/tri/disks.htm]. TRI point and nonpoint release categories were summed to calculate total reported releases to air. Any reported air, water, publicly owned treatment work, land, underground injection, or accidental release was considered an environmental release.

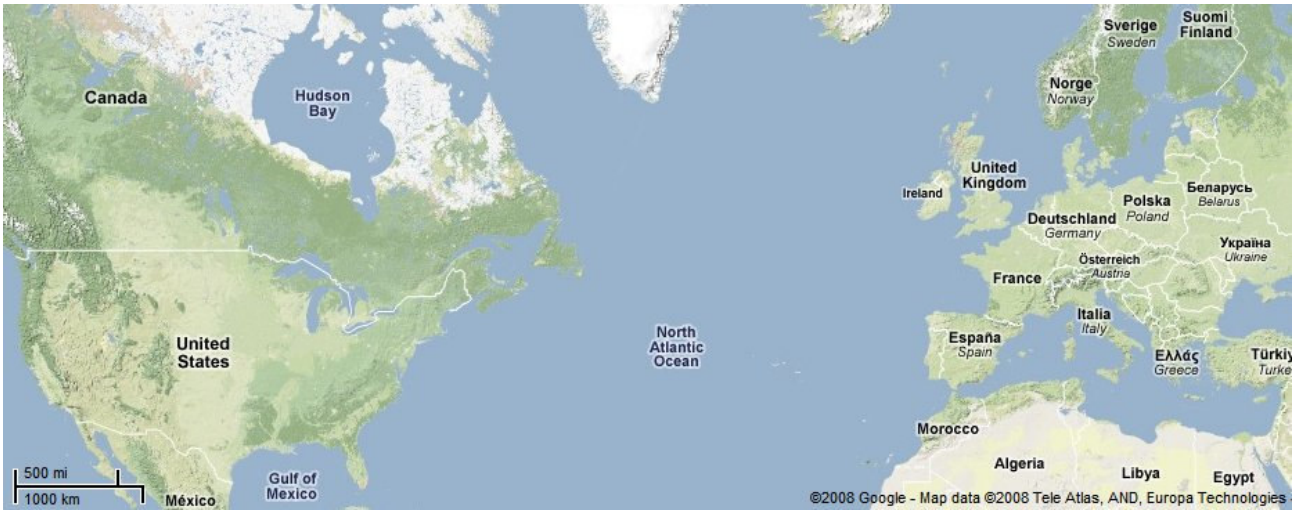
[16] The TRI list for 1995 included 578 chemicals and 28 chemical categories. Reporting requirements do not apply to all sources of a listed chemical, but only to manufacturing facilities in specific industrial sectors (SIC codes 20-39) with more than 10 employees. Over 50% of facilities involved in chemical manufacturing and processing have fewer than 10 employees and are not required to report under TRI.

[17] U.S. EPA, Office of Solid Waste and Office of Pollution Prevention and Toxics, Waste Minimization and Prioritization Tool: Software and User's Guide and System Documentation, Draft (Washington, D.C.: U.S. EPA, 1997), Internet/WWW [address: http://www.epa.gov/epaoswer/hazwaste/minimize/tool/tooldown.htm].

Denison
Attachment D

Across the Pond

ASSESSING REACH'S FIRST BIG IMPACT ON U.S. COMPANIES AND CHEMICALS



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Addendum 093

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This report is available online at www.edf.org/AcrossThePond.

Across the Pond

ASSESSING REACH'S FIRST BIG IMPACT ON U.S. COMPANIES AND CHEMICALS

SEPTEMBER 2008
UPDATED JANUARY 2009

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ENVIRONMENTAL DEFENSE FUND

finding the ways that work

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Tables (in separate document available at www.edf.org/AcrossThePond):

Preface—Why the Update?

This report was updated in January 2009 to incorporate new data from the 2006 reporting cycle under the Inventory Update Rule (IUR), which was finally released by the U.S. Environmental Protection Agency on December 30, 2008. The new data reflect production and import for calendar year 2005. The first version of *Across the Pond*, released in September 2008, utilized data from the 2002 IUR reporting cycle, reflecting production and import in calendar year 2001. Following this preface, the remainder of this updated report, as well as the accompanying data tables, now reflect data from 2006 IUR reporting cycle.

This preface and Appendix 1 describe differences and changes between the two data sets. Two major changes in the reporting rules from 2002 to 2006 are important to understand:

- The volume threshold for reporting was raised from 10,000 pounds per site in the 2002 reporting cycle to 25,000 pounds per site in the 2006 cycle. Companies below these thresholds were not required to report their production or import. For this reason, the number of chemicals reported dropped significantly in the 2006 cycle.
- For the first time in the 2006 cycle, inorganic as well as organic chemicals were required to be reported (if above the volume threshold). Hence many additional inorganic chemicals (including some on the SIN List) appear in the new data, although not enough to offset the reduction in number of chemicals reported due to the raising of the volume threshold.

With respect to the SIN List chemicals, the overlap with the IUR chemicals changed considerably between the 2002 and 2006 cycles. Some SIN List chemicals reported in 2002 were not reported in 2006, and vice versa. While some of the observed differences are likely explained by the changes in reporting rules just noted, others are more mysterious.

Appendix 1 provides more details on the comparison of SIN List chemicals reported in 2002 and 2006.

Summary

The European Union's new chemicals regulation—Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)[1]—will require companies to *register* all chemicals they place on the EU market in amounts above one metric ton. EU government officials will have authority to *evaluate* these registrations to determine whether companies have demonstrated that production and use of their chemicals is safe. REACH's requirements apply not only to EU-based chemical producers and importers, but also to U.S. companies that export to the EU.

A hallmark of REACH is its identification of so-called "substances of very high concern" (SVHCs). REACH's intent is ultimately to subject SVHCs to *authorization*—that is, to allow them to be used only where each use has been specifically authorized. Chemicals meeting the criteria for SVHCs—whether made in the EU or imported from the U.S.—are to be placed on a "candidate list" of chemicals intended eventually to be subject to authorization.

As one of the first formal activities taking place under REACH, EU officials recently proposed an initial candidate list of SVHCs. The initial list contained only 16 substances, however, and while the list is expected to grow over time, 15 of the proposed chemicals were retained on the final version of the initial list.[2] In response, European environmental NGOs developed a longer list of nearly 300 chemicals that meet the SVHC criteria, which they have dubbed the "SIN List 1.0." SIN stands for "Substitute It Now," reflecting the groups' interest in promoting safer alternatives to SVHCs wherever possible.[3] The "1.0" suffix denotes that the list is not exhaustive and is a work in progress. This list is also the first public attempt to identify specific chemicals that qualify as SVHCs under REACH.

This report explores one of the first and most significant ways that REACH will impact the U.S.: It uses the SIN List to determine which chemicals and companies in the U.S. are likely to be affected by the development of the REACH candidate list and ultimately by authorization.

The analysis presented in this report supports the following findings:

Many, and likely most, SIN List chemicals are in active commerce in the U.S.

- **At least 80% of the SIN List chemicals appear on the U.S. Toxic Substances Control Act (TSCA) Inventory.**
- **A minimum of 37% of the SIN List chemicals are currently being produced or imported in the U.S. above 25,000 pounds annually.**

At least 77 SIN List chemicals are produced annually in amounts of one million or more pounds, and at least 14 exceed one billion pounds annually.

At least 235 companies are producing or importing SIN List chemicals in the U.S.

Some companies are associated with multiple SIN List chemicals—as many as 16 per company.

Many SIN List chemicals are produced or imported by multiple companies at numerous sites—as many as 41 companies at 62 separate sites.

SIN List chemicals are produced or imported in 42 states as well as Puerto Rico and the Virgin Islands, at as many as 100 sites per state. The number of SIN List chemicals per state varies from 1 to 48.

Only about one-third of the SIN List chemicals on the TSCA Inventory have been subject to testing or other data development programs under TSCA.

Only two SIN List chemicals have been subject to any regulation under TSCA, and even these only under narrow conditions.

Nearly all of the SIN List chemicals have already been formally designated by EU officials as meeting the criteria used to define substances of very high concern under REACH. REACH's stated intention is ultimately to allow the use of such substances only when specifically authorized on a use-by-use basis. In marked contrast, the U.S. Environmental Protection Agency (EPA) has undertaken only very limited activity to address these chemicals.

Taken together, our findings suggest that REACH's focus on SVHCs can be expected to have a major impact on chemical production and use in the U.S. and on the companies that make, export or import chemicals. Hundreds of companies in the United States produce or import hundreds of chemicals designated as dangerous by the European Union (EU), and hence will be directly impacted by controls imposed on such chemicals under the EU's new chemicals regulation.

Introduction

REACH, the European Union's sweeping chemicals policy reform, took effect last year. A hallmark of REACH is its identification of so-called "substances of very high concern" (SVHCs). REACH's intent is ultimately to subject SVHCs to *authorization*—that is, to allow them to be used only when specifically authorized.[4]

SVHCs are chemicals identified by REACH as:

- Carcinogenic, mutagenic or toxic to reproduction (CMR),[5]
- Persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB),[6] or
- Identified, on a case-by-case basis, as causing effects to human health or the environment of an *equivalent level of concern* as those above (e.g. endocrine disrupters).[7]

Chemicals meeting these criteria are eligible to be placed on a "candidate list" of chemicals intended eventually to be subject to authorization.

One of the first formal activities taking place under REACH is the development of the initial "candidate list." The European Chemicals Agency (ECHA) intends to publish the first version of this list by the end of October 2008. To that end, in June ECHA proposed 16 substances for listing, presented dossiers developed by various EU member states, and invited public comment.[8] ECHA indicates that each of these chemicals meets the CMR, PBT or vPvB criteria.[9] All of them already have been so designated officially by the EU authorities.[10]

The 16 chemicals proposed by ECHA for the first edition of the candidate list represent only a small fraction of the chemicals on the EU's official lists of SVHCs, however.[11] The International Chemical Secretariat (known as ChemSec), a Sweden-based nongovernmental organization (NGO), in cooperation with other EU NGOs, has developed its own version of the candidate list, in an effort to speed up the process of adding SVHCs to the official list. Representing the first public attempt to identify specific chemicals that qualify as SVHCs under REACH, and in acknowledgment that the list will change over time, ChemSec has dubbed its list the "SIN List 1.0".[12] SIN stands for "Substitute It Now," reflecting ChemSec's interest in promoting safer alternatives to SVHCs wherever possible.

The SIN List includes primarily CMRs, PBTs and vPvBs already designated by EU authorities, but also includes additional chemicals that ChemSec determined meet these criteria or those for substances of equivalent concern.[13]

The SIN List includes 267 entries, each for an individual chemical or a group of closely related substances:

- 220 are CMRs,
- 11 are PBTs, two of which are also vPvBs,
- six substances are both CMRs and PBTs and
- 30 are "equivalent concern" substances.

Why this report?

REACH's requirements will apply equally to EU-based chemical production and to import of chemicals into the EU. For this reason it will directly affect many U.S. chemical producers and users.

ChemSec's SIN List identifies chemicals that—based on already available data—can reasonably be expected to be subject to authorization under REACH. This report uses the SIN List to elucidate the potential impact of the candidate list and of REACH authorization on chemicals and companies in the U.S. We do so by exploring the following questions:

- Which of the SIN List chemicals are in commerce in the U.S.?
- In what amounts are these chemicals produced or imported in the U.S.?
- Which companies have reported producing or importing them, and at how many sites?
- In which states are SIN List chemicals produced or imported?

We also look at the extent to which SIN List chemicals have been or are being scrutinized or addressed by the U.S. Environmental Protection Agency (EPA). Specifically, we ask:

- Which of the SIN list chemicals have been tested in the U.S.?
- Which SIN List chemicals have been regulated by EPA, resulting either in limits placed on their production or use or in imposition of notification requirements? How many have been exempted from regulatory requirements?

Appendix 2 describes how we conducted our analysis and the sources of data we used.

Limitations to our analysis

Our analysis is based on the latest publicly available U.S. information provided by EPA (see Appendix 2). Unfortunately, this reliance constrains several aspects of our analysis. The three main limitations are the following:

- The most recent public data on U.S. chemical production and import are somewhat dated, as they were collected by EPA in 2006 for activity during the single calendar year 2005. Given the dynamic nature of the chemical market, both from year to year and between 2005 and the present, **some of the data we report here on chemicals, their production/import volumes and their associated companies may well have changed.**
- Any chemical produced or imported in the U.S. in an amount below 25,000 pounds per year at a given site was not required to be reported at all. Hence, EPA's data and our analysis do not include such chemicals or their producers/importers.
- Under TSCA, U.S. companies have wide latitude to claim information they report to EPA as confidential business information (CBI). EPA rarely challenges such claims and must not publicly disclose information claimed as CBI. Thousands of chemicals are not included in the public version of the TSCA Inventory because their producers have claimed the chemical identities to be CBI. Similarly, companies can also hide their own identities by claiming

their production or import of a chemical to be CBI. **Hence, the chemicals and companies we list in this report represent only the subset that are not claimed CBI**.

It is important to bear these limitations in mind when reading this report.

Analysis

1. Which SIN List chemicals are in commerce in the U.S.?

Finding: Many, and likely most, SIN List chemicals are in active commerce in the U.S.:

- **At least 80% of the SIN List chemicals appear on the U.S. TSCA Inventory.**
- **At least 38% of the SIN List chemicals were reported as produced or imported in quantities exceeding 25,000 pounds in 2005 (the most recent year for which EPA has collected data).**

Details: Our analysis utilized 283 distinct CAS numbers representing SIN List substances (see Appendix 2 for details). Of the 283 CAS numbers on the SIN List, 226 (80%) appear on the latest (July 2008) public version of the U.S. TSCA Inventory.[14] Hence, these chemicals have been in U.S. commerce at some time since the Inventory was developed in 1979. A list of these CAS numbers is provided in Table 1.[15]

This figure is likely an underestimate of the number of SIN List chemicals in the U.S. because:

- Certain types of chemicals are exempted from TSCA and hence would not have been reported at the time the Inventory was established.
- The identities of many chemicals on the TSCA Inventory are claimed confidential and hence do not appear on the public version.[16]

On the other hand, not all of these chemicals may currently be in commerce in the U.S. Because it is a cumulative listing over time, the TSCA Inventory contains an unknown but likely significant number of chemicals no longer in active production or use.

Unfortunately, EPA updates the TSCA Inventory infrequently and in a partial manner. Starting in 1986, when EPA promulgated the Inventory Update Rule (IUR), companies were required to report to EPA once every four years the identity of and volume of each non-exempt organic chemical substance they produced or imported in annual amounts of 10,000 pounds or more at each site they owned or controlled. Beginning in 2006, however, the reporting frequency was reduced from once every four to once every five years, and the volume threshold was raised from 10,000 to 25,000 pounds per year per site. IUR information applies only to the one year preceding the reporting year.[17]

Based on the most recent publicly available IUR data, collected in 2006 and reflecting 2005 activity, 107 (38%) of the SIN List CAS numbers were reported as produced or imported above the IUR threshold of 25,000 pounds. See Table 1.

This number is likely an underestimate of the number of SIN List chemicals in active commerce in the U.S. because:

- It is very likely that some of the SIN List chemicals are produced or imported in amounts below the 25,000 pound reporting threshold. In general, the number of chemicals produced or imported is greater for smaller volumes.
- Some categories of chemicals and companies have been exempted from IUR reporting.[18]
- Chemicals with identities claimed confidential do not appear on the public version of the IUR database.[19]

Changes in production volume since 2005 may also influence our count. Some chemicals below the reporting threshold in 2005 may now be above it, and vice versa. Extensive fluctuations have been documented in which chemicals are reported from one IUR reporting cycle to the next.[20]

2. In what amounts are SIN List chemicals produced or imported in the U.S.?

Finding: Many SIN List chemicals are produced or imported in substantial quantities in the U.S.

Details: Under the IUR, EPA requires companies to report the quantity of each chemical they produced or imported in amounts exceeding the reporting threshold. However, EPA only reports *aggregate* volume data to the public, summed up across all reporting producers and importers. Moreover, these data are only provided in broad volume ranges, further limiting their utility. Nevertheless, the IUR data do provide a rough estimate of the level of production and import of SIN List chemicals in the U.S.

For the 226 SIN List CAS numbers on the TSCA Inventory, Table 1 provides a breakdown of the number in each aggregate volume range. These can be assigned to EPA's even broader volume classifications of high-, medium- and low-production volume (HPV, MPV and LPV, respectively), as follows:

Production volume	Pounds per year	# of CAS numbers	% of total
High	>1 million	77[21]	34%
Medium	25,000—1 million	30	13%
Low	<25,000	119*	53%

* may include chemicals not currently in commerce

Note that, because LPV chemicals are not required to be reported under the IUR, some of the SIN List chemicals identified as LPV may not be in active commerce in the U.S.

Fourteen of the SIN List chemicals are produced and imported in the U.S. in huge quantities, exceeding one *billion* pounds annually. These chemicals are listed below:

Chemical name	CAS #
Bisphenol A	80-05-7
Styrene	100-42-5
Ethanol, 2-ethoxy-, 1-acetate	111-15-9
Formaldehyde	50-00-0
Aniline	62-53-3
1,3-Butadiene	106-99-0
1,2-Dichloroethane (aka Ethylene dichloride)	107-06-2
Acrylonitrile	107-13-1
2,4-Dinitrotoluene	25321-14-6
Carbon monoxide	630-08-0
Benzene	71-43-2
Vinyl chloride	75-01-4
Ethylene oxide	75-21-8
Propylene oxide	75-56-9

3. Which companies produce or import SIN List chemicals in the U.S.?

Finding: Many companies are involved in production or import of SIN List chemicals in the U.S. Some companies are associated with multiple SIN List chemicals, and many SIN List chemicals are produced or imported by multiple companies at numerous sites.

Details: A total of 235 companies reported producing or importing one or more SIN List chemicals in the U.S. in 2005. Of these, 114 companies reported producing such chemicals, while 135 reported importing them. Thirty-eight companies claimed as CBI the information as to whether they manufactured or imported a given chemical.[22]

Across the 235 companies, the number of SIN List CAS numbers publicly reported per company varied from 1 to 16. The top eight companies were as follows:

Company	# Manufactured	# Imported	# CBI	Total*
BASF Corporation	3	13	0	16
The Dow Chemical Company	11	11	0	14
E. I. du Pont de Nemours and Co.	9	5	0	12
Huntsman Corporation	4	6	0	9
Chemtura Corporation (formerly Great Lakes Chemical)	0	0	9	9
ICC Chemical Corporation	0	8	0	8
Ferro Corporation	5	2	0	7
Albemarle Corporation	4	4	1	7

* Numbers do not add to total because a chemical may be produced and imported by the same company.

Table 2 provides a full list of companies and the SIN List CAS numbers they reported producing or importing in 2005.[23]

One or more companies publicly reported producing or importing all but two of the 107 CAS numbers on the SIN List that exceeded the reporting threshold. For those two chemicals, the company or companies producing or importing them evidently opted to hide their identities by claiming their association with the chemicals confidential. It is also possible that additional companies produce or import other SIN List chemicals, but chose to mask their identity.

Finally, it is likely that the companies shown in Table 2 or companies not listed produced or imported these or additional SIN List chemicals, but cannot be identified because they fell below the reporting threshold or qualified for a reporting exemption.

This analysis demonstrates that a large number of companies are involved in production or import of SIN List chemicals in the U.S. Some companies are associated with many SIN List chemicals.

Similarly, many SIN List chemicals are produced or imported in the U.S. by many different companies and at numerous different sites. Below are listed the 12 SIN List chemicals for which production or import was reported at 13 sites or more:

Chemical name	CAS #	# Companies	# Sites
Benzene	71-43-2	41	62
Styrene	100-42-5	19	25
1,3-Butadiene	106-99-0	17	22
Formaldehyde	50-00-0	16	42
Ethylene dichloride	107-06-2	15	22
Nickel monoxide	1313-99-1	14	24
Hexane	110-54-3	13	15
Bisphenol A	80-05-7	10	13
Vinyl chloride	75-01-4	9	13
Ethylene oxide	75-21-8	9	13
Nonylphenol ethoxylate	9016-45-9	7	23
Carbon monoxide	630-08-0	4	14

Once again, these numbers should be viewed as minimums; they do not reflect companies or sites that hid their identities by claiming their association with these chemicals to be confidential.

Table 1 shows the number of companies manufacturing and importing each SIN List CAS number in the U.S., as well as the total number of sites involved.

4. In which states are SIN List chemicals produced or imported?

Finding: SIN List chemicals are produced or imported in 42 states as well as Puerto Rico and the Virgin Islands, at as many as 100 sites per state. The number of SIN List chemicals per state varies from 1 to 48. The number of states producing or importing a given chemical varies from 1 to 22.

Details: SIN List chemicals are produced or imported in more than four-fifths of U.S. states, as well as Puerto Rico and the Virgin Islands, typically at multiple sites within a state. Below are listed the eight states with the most SIN List chemicals; also listed are the number of sites of production or import for such chemicals in each state:

	# of Chemicals				*# of Sites*			
	Produced	Imported	CBI	Total*	Produced	Imported	CBI	Total*
Texas	29	31	10	48	65	35	8	100
New Jersey	8	26	3	35	6	12	3	21
Ohio	11	19	2	30	12	15	2	27
Louisiana	21	7	4	27	31	6	4	38
New York	2	22	3	25	2	12	2	15
North Carolina	8	9	6	22	10	5	2	16
Pennsylvania	12	13	2	20	10	11	2	21
Michigan	5	12	1	15	3	2	1	6

* Numbers do not add to total because a chemical may be produced and imported in the same state or site.

Table 3 shows the same data for all 42 states, Puerto Rico and the Virgin Islands.[24]

Some SIN List chemicals are produced or imported in many different states. Below are the six SIN List chemicals produced or imported in the most states:

		# of states			
Chemical name	CAS #	Produced	Imported	CBI	Total*
Formaldehyde	50-00-0	19	8	2	22
Nonylphenol ethoxylate (NPE)	9016-45-9	1	16	1	17
Benzene	71-43-2	13	8	3	16
Styrene	100-42-5	3	12	1	13
Di-(2-ethylhexyl) phthalate (DEHP)	117-81-7	3	6	1	10

* Numbers do not add to total because a chemical may be produced and imported in the same state.

As before, the numbers above should be viewed as minimums; they do not reflect companies or sites that hid their identities by claiming their association with these chemicals to be confidential.

Table 4 shows the SIN List chemicals produced or imported in each state, along with their associated companies.[25]

5. Which of the SIN list chemicals have been tested under TSCA?

Finding: Only about a third of the SIN List chemicals on the TSCA Inventory have been subject to testing or other data development programs under TSCA.

Details: Of the 283 SIN List CAS numbers, 234 (83%) are drawn from official EU lists of CMRs, PBTs or vPvBs.[26] These findings indicate that these chemicals have already been assessed, based on data deemed sufficient by EU authorities to determine that they meet the criteria defining SVHCs. The remaining 49 SIN List CAS numbers were added based on evidence that ChemSec deemed sufficient to indicate that the substances either meet CMR, PBT or vPvB criteria or satisfy the criteria for "equivalent concern." Of these, 13 have already been formally prioritized by EU officials as likely or potential endocrine disruptors.[27]

To what extent have data been developed for these chemicals under TSCA?

Mandatory testing
Since TSCA was enacted, EPA has subjected about 200 chemicals to mandatory testing using its Section 4 authorities, either through issuing test rules or including testing requirements in Enforceable Consent Agreements.[28] We found that 38 SIN List CAS numbers are among those subjected to mandatory testing by EPA (see Table 1 and Appendix 2 for details).

The amount of testing required for these chemicals has varied widely, from a test for single endpoints to more extensive testing. In very few cases, however, has EPA required the development of even a minimal base set of hazard data.

Voluntary testing
EPA has also pursued voluntary efforts to develop data, most notably through its HPV Challenge program.[29] We found that 77 of the SIN List CAS numbers are among the chemicals eligible for sponsorship under the Challenge (see Table 1 and Appendix 2 for details). Here is the status of these 77 CAS numbers:

- 72 have been sponsored:
  - 42 have been sponsored under the Challenge.
  - 30 more have been sponsored under a sister HPV program that operates under the auspices of the Organization for Economic Cooperation and Development (OECD).
- Five are not sponsored and are so-called "orphans."

Of the 72 sponsored HPV CAS numbers:

- 61 have final data sets (for those under the Challenge) or agreed assessments (for those under the OECD program).
- Nine are in the pipeline but have not been finalized.
- Two have not had even initial information submitted.

Both the Challenge and the OECD HPV programs are intended to develop a basic set of hazard data for each HPV chemical, called the Screening Information Data Set, or SIDS. This data set was developed through an international consensus process to constitute the minimum amount of data needed to conduct a screening-level hazard assessment for a chemical.[30] While most HPV chemicals with completed assessments appear to have such a minimum dataset, significant data gaps remain. Of the first 300 HPV chemicals assessed by EPA using the Challenge data, EPA found gaps remaining in the supposedly final data sets submitted for at least 35% of them.[31]

These two lists—38 CAS numbers subject to mandatory testing and 70 CAS numbers with completed or in-progress data development under the Challenge—overlap, with 28 CAS numbers on both lists. Taken together, then, 80 of the SIN List CAS numbers have been subject to a mandatory or voluntary testing or data development program under TSCA.

In sum, of the 226 SIN List CAS numbers on the TSCA Inventory, data have been or are being developed under TSCA for 35% (80 of 226) of them. Little or no data development appears to have occurred under TSCA for the remaining SIN List CAS numbers. This number is much smaller than the 234 SIN List chemicals already deemed by EU authorities to be sufficiently well-characterized to designate them SVHCs.

Fourteen additional SIN List CAS numbers that are not part of the HPV Challenge are sponsored under the OECD HPV program (see Table 1). Nine of these have final OECD assessments, while the other five are in earlier stages of data development.[32] Counting these, 94 of the SIN List chemicals have been or are being subject to some type of data development either in the U.S. under TSCA or through the OECD voluntary HPV program.

6. Which SIN List chemicals have been regulated by EPA, resulting in either limits placed on their production or use or notification requirements? How many have been exempted from regulatory requirements?

Finding: Only a small number of SIN List chemicals have been subject to any regulation under TSCA, and even these only under narrow conditions.

Details: A total of 12 CAS numbers on the SIN List have been subject to regulation under Section 6 of TSCA (see Appendix 2 and Table 1). These CAS numbers correspond to only two groups of related substances, however:

- seven CAS numbers covering various forms of asbestos; and
- five CAS numbers covering various chromium compounds.

Moreover, the regulations covering both of these substance groups are very limited in scope:[33]

- **Only uses of asbestos in products no longer in commerce** are regulated under TSCA; EPA attempted to ban all uses of asbestos, but its regulation was vacated by the Fifth Circuit Court of Appeals in 1991.
- EPA banned **only those hexavalent chromium-based water treatment chemicals for use in comfort cooling towers** in 1990. The regulation does not apply to any other uses of these compounds, to any other hexavalent chromium compounds, or to any trivalent chromium compounds.

EPA has subjected 20 of the SIN List CAS numbers to so-called Significant New Use Rules, or SNURs (see Table 1 and Appendix 2 for details).[34] SNURs do not themselves restrict production or use. They only require that companies that produce or use a chemical covered by the SNUR notify EPA if such production or use does not comport with conditions specified in the SNUR. This notification requirement provides EPA with an opportunity to review the conditions of production or use and decide whether or not to impose restrictions.

Finally, EPA has exempted manufacturers and processors of eight SIN List CAS numbers from requirements to report their activities under the TSCA IUR (see Table 1). These chemicals are all octyl- and nonylphenol ethoxylates, which are toxic to aquatic organisms and break down into octyl- and nonylphenols that are both more persistent and more toxic than their parent compounds and exhibit endocrine-disrupting activity.[35] EPA exempted these chemicals because they are polymers, which are generally exempt from IUR reporting based on the presumption that they are unlikely to be bioavailable—an assumption that, at least for these chemicals and their breakdown products, is not supported by the available evidence.

From this discussion it is clear that only a small number of SIN List chemicals have been subject to any regulation under TSCA, and even these only under very narrow conditions.

Conclusion

Our analysis has documented that there is substantial production and use in the U.S. of over 100, and likely many more, chemicals already identified by the EU as "substances of very high concern" (SVHCs). Many of these chemicals are produced in very large quantities in the U.S., by many different companies at many sites and in many states. The intent of REACH, the EU's new chemicals policy, is ultimately to allow the use of such substances only when specified authorized on a use-by-use basis.

In marked contrast, EPA has undertaken only very limited activity to address these chemicals. Only about a third of SIN List chemicals on the TSCA Inventory have been subjected to any degree of either mandatory or voluntary testing under TSCA. Only the various forms of asbestos and certain hexavalent chromium compounds have been subjected to any regulation, and even then only for very narrow uses of these dangerous substances.

Taken together, our findings suggest that REACH's focus on SVHCs can be expected to have a major impact on chemical production and use in the U.S. and on the companies that make, export or import chemicals. Hundreds of companies in the United States produce or import hundreds of chemicals designated as dangerous by the European Union (EU), and hence will be directly impacted by controls imposed on such chemicals under the EU's new chemicals regulation.

Appendix 1: Comparison of SIN List chemicals reported in 2002 and 2006 under EPA's Inventory Update Rule (IUR)

As described in the Preface, with respect to the SIN List chemicals, the overlap of SIN List chemicals with the chemicals reported under these two successive cycles of reporting under the IUR changed considerably. Numerous SIN List chemicals reported in 2002 were not reported in 2006, and vice versa. While some of the observed differences are likely explained by the changes in reporting rules described in the Preface, others are more mysterious.

SIN List chemicals appearing in one IUR reporting cycle but not the other are shown in the Table below. The comparison can be summarized as follows:

- 18 SIN List CAS numbers that are on the 2006 IUR were not on the 2002 IUR. Some possible explanations:[36]
    - 12 of these are inorganic chemicals and hence were likely reported for the first time in 2006.
    - All but one of the remaining six CAS numbers were reported in the lowest volume range (<500,000 pounds aggregated across all reporting sites), while the last one was reported in the second lowest range (between 500,000 and 1 million pounds). It is possible that the production volume for these CAS numbers was below the reporting threshold in 2002 but rose above it in 2006.
- 29 SIN List CAS numbers that were on the 2002 IUR are not on the 2006 IUR. Some possible explanations:
    - Two of these chemicals are Perfluorooctane sulfonic acid (PFOS), CAS# 1763-23-1, and Perfluorooctane sulfonamide (PFOSA), CAS# 4151-50-2, both of which were phased out of production in 2002 by their only U.S. producer, 3M Company.[37]
    - Another of these chemicals is Octabromodiphenylether, CAS# 32536-52-0, which was phased out of production in 2004 by its only U.S. producer, Great Lakes Chemical (now Chemtura).[38]
    - A fourth chemical is a polymer, and was likely erroneously reported in 2002. Polymers are exempt from IUR reporting.[39]
    - Of the remaining 25 CAS numbers, 15 were reported in 2002 in the lowest aggregate production/import volume range (between 10,000 and 500,000 pounds), and hence may not have met the higher reporting threshold that applied in the 2006 cycle.
    - 9 of the remaining 10 CAS numbers are for chemicals that were reported as high production volume (HPV) chemicals exceeding 1 million pounds of aggregate production/import in 2002.
        - 5 were in the 1-10 million pound aggregate volume range.
        - 2 were in the 10-50 million pound aggregate volume range.
        - 1 was in the 50-100 million pound aggregate volume range.
        - 1 was in the 100-500 million pound aggregate volume range.

      No clear explanation for the "disappearance" of these HPV chemicals is apparent, especially as they include a number of quite common chemicals (see Table below).[40]

SIN List Chemicals reported on the 2006 but not in the 2002 IUR reporting cycle

CAS #	Name(s)	2006 Reported Volume	Comment (see text)
87-61-6	1,2,3-trichlorobenzene	<500K	--
94-59-7	safrole; 5-allyl-1,3-benzodioxole	<500K	--
556-52-5	2,3-epoxypropan-1-ol; glycidol; oxiranemethanol	<500K	--
1303-28-2	diarsenic pentaoxide; arsenic pentoxide; arsenic oxide	10M - <50M	inorganic
1304-56-9	beryllium oxide	<500K	inorganic
1313-99-1	nickel monoxide	10M - <50M	inorganic
7440-41-7	beryllium	<500K	inorganic
7440-43-9	cadmium (pyrophoric); cadmium (non-pyrophoric); cadmium oxide (non-pyrophoric)	1M - <10M	inorganic
7646-79-9	cobalt dichloride	1M - <10M	inorganic
7758-97-6	lead chromate	<500K	inorganic
7789-06-2	strontium chromate	<500K	inorganic
9002-93-1	4-tert-octylphenolethoxylate	<500K	--
9036-19-5	nonidet P-40	500K - <1M	--
10124-43-3	cobalt sulphate	1M - <10M	inorganic
12035-72-2	nickel subsulphide; trinickel disulphide	1M - <10M	inorganic
16812-54-7	nickel sulphide	<500K	inorganic
24613-89-6	dichromium tris(chromate); chromium III chromate; chromic chromate	<500K	inorganic
25154-52-3	nonylphenol	<500K	--

SIN List Chemicals reported on the 2002 but not in the 2006 IUR reporting cycle

CAS #	Name(s)	2002 Reported Volume	Comment (see text)
57-14-7	N,N-dimethylhydrazine	10K - 500K	< 2006 threshold?
60-09-3	4-aminoazobenzene; 4-phenylazoaniline	10K - 500K	< 2006 threshold?
75-12-7	formamide	>1M - 10M	--
79-16-3	N-methylacetamide	10K - 500K	< 2006 threshold?
79-46-9	2-nitropropane	>10M - 50M	--
91-94-1	3,3'-dichlorobenzidine; 3,3'-dichlorobiphenyl-4,4'-ylenediamine	10K - 500K	< 2006 threshold?
95-80-7	4-methyl-m-phenylenediamine; 2,4-toluenediamine	10K - 500K	< 2006 threshold?
96-09-3	styrene oxide; (epoxyethyl)benzene; phenyloxirane	10K - 500K	< 2006 threshold?

SIN List Chemicals reported on the 2002 but not in the 2006 IUR reporting cycle (continued)

CAS #	Name(s)	2002 Reported Volume	Comment (see text)
96-18-4	1,2,3-trichloropropane	>1M - 10M	--
100-63-0	phenylhydrazine	>1M - 10M	--
107-30-2	chlormethyl methyl ether; chlorodimethyl ether	>10M - 50M	--
112-49-2	1,2-bis(2-methoxyethoxy)ethane; triethylene glycol dimethyl ether (TEGDME); triglyme	10K - 500K	< 2006 threshold?
120-12-7	anthracene, pure	10K - 500K	< 2006 threshold?
126-99-8	Chloroprene (stabilized); 2-chlorobuta-1,3-ciene	>100M - 500M	--
133-49-3	pentachlorobenzenethiol	10K - 500K	< 2006 threshold?
151-56-4	ethyleneimine; aziridine	>1M - 10M	--
625-45-6	methoxyacetic acid	>500K - 1M	--
764-41-0	1,4-dichlorobut-2-ene	>50M - 100M	--
1120-71-4	1,3-propanesultone; 1,2-oxathiolane 2,2-dioxide	10K - 500K	< 2006 threshold?
1461-22-9	tributyltin chloride	>1M - 10M	--
1589-47-5	2-methoxypropanol	10K - 500K	< 2006 threshold?
1763-23-1	perfluorooctane sulfonic acid (PFOS)	10K - 500K	phased out 2002
4151-50-2	perfluorooctane sulfonamide (PFOSA)	10K - 500K	phased out 2002
12656-85-8	lead chromate molybdate sulfate red; C.I. Pigment Red 104	10K - 500K	< 2006 threshold?
17570-76-2	lead(II) methanesulphonate	10K - 500K	< 2006 threshold?
21145-77-7	tonalid	10K - 500K	< 2006 threshold?
32536-52-0	diphenyl ether, octabromo derivative	>1M - 10M	phased out 2004
68412-54-4	poly(oxy-1,2-ethanediyl), alpha-(nonylphenyl)-omega-hydroxy-, branched	>1M - 10M	exempt from IUR reporting
90640-80-5	anthracene oil	10K - 500K	< 2006 threshold?

Appendix 2: How we did our analysis

The SIN List includes 267 entries, each for an individual chemical or a group of closely related substances:

- 220 CMRs,
- 11 PBTs, two of which are also vPvBs,
- six substances that are both CMRs and PBTs and
- 30 "equivalent concern" substances.

To conduct our analysis, we made three adjustments. First, we were not able to include eight entries for CMR substances that lack a Chemical Abstract System (CAS) Registry Number, because the cross-comparisons among lists that are the basis of our analysis require such identifiers. Second, some SIN List entries include more than one CAS number, one for each of two or more closely related substances grouped together in a given entry. Our analysis used all specified CAS numbers in such groups. Third, asbestos is listed on the TSCA Inventory as CAS# 1332-21-4 but not as any of the seven CAS numbers listed on the SIN List for various forms of asbestos (12001-28-4, 12001-29-5, 12172-73-5, 132207-32-0, 77536-66-4, 77536-67-5 and 77536-68-6). We therefore used CAS# 1332-21-4 instead of the seven SIN List CAS numbers.[41] Applying these adjustments yielded a total of 283 distinct CAS numbers.[42]

We compared this list of 283 CAS numbers to the following chemical lists:

- The TSCA Inventory. We used the most recent public version of the Inventory, dated July 2008.[43]
- Chemicals produced or imported in the U.S. We used the latest publicly available data from EPA on chemicals produced in or imported into the U.S. and the companies that reported producing or importing them, in 2005. These data are periodically collected by EPA under its TSCA Inventory Update Rule (IUR).[44] The IUR data provide:
    - the identity of reported chemicals, by name and CAS number;
    - the volume of production and import, aggregated across all reporting producers and importers and reported as a range in pounds for the reporting year;
    - the names of reporting companies for each chemical, and whether they reported producing or importing the chemical; and
    - the location of each facility of each company that reported producing or importing each chemical.
- Chemicals subject to mandatory testing under TSCA. We could find no single authoritative and complete list of such chemicals on EPA's website, so instead we compiled a list using four sources:
    - chemicals flagged on the TSCA Inventory as currently subject to a mandatory test rule issued by EPA under Section 4 of TSCA;
    - chemicals listed in a PDF document posted on EPA's website titled "TSCA Section 4 Chemicals" on a page that reports results of testing conducted under Section 4 test rules;[45]
    - chemicals listed on EPA's "Current List of Chemical Substances Subject to TSCA Section 12(b) Export Notification Requirements" that are indicated as currently

subject either to a test rule or to data development under an Enforceable Consent Agreement (ECA) issued under Section 4 of TSCA;[46] and
    - chemicals listed in a table posted on EPA's website indicating sunset dates for Section 12(b) requirements under TSCA, which are tied to completion of data development under Section 4 actions.[47]

  While these lists had considerable overlap, each also had unique listings. Chemicals indicated on any of these four lists as subject to testing requirements were included.
- Chemicals tested under voluntary programs. We used Environmental Defense Fund's HPVTracker[48] to determine the status of SIN List chemicals that fall under EPA's High Production Volume (HPV) Challenge Program. The HPVTracker draws data from EPA's Challenge webpages and from the database of the OECD HPV program.[49] The status of additional SIN List chemicals that do not fall under the HPV Challenge was determined using the OECD HPV database.
- Chemicals regulated under Section 6 of TSCA. We identified any SIN List CAS numbers that carried a flag on the TSCA Inventory indicating it is subject to a regulation issued by EPA under Section 6. Two classes of chemicals were so flagged:
    - various forms of asbestos (seven CAS numbers);[50] and
    - various hexavalent chromium compounds (five CAS numbers).[51]
- Chemicals subject to Significant New Use Rules under TSCA. We identified any SIN List CAS numbers that carried a flag on the TSCA Inventory indicating it is subject to a proposed or final Significant New Use Rule issued by EPA under TSCA. Companies that produce or use a chemical covered by a SNUR must notify EPA if such production or use does not comport with conditions specified in the SNUR.
- Chemicals exempt from reporting under the Inventory Update Rule. We identified any SIN List CAS numbers that carried a flag on the TSCA Inventory indicating it is exempt from IUR reporting.

Endnotes

[1] REACH is an EU-wide regulation adopted in December 2006. The final text of REACH is available at eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_39620061230en00010849.pdf. For more information about how REACH works and how it compares to the U.S. Toxic Substances Control Act (TSCA), see Denison, R.A. (2007) *Not That Innocent: A Comparative Analysis of Canadian, European Union and United States Policies on Industrial Chemicals* (Environmental Defense, Washington, DC), at www.edf.org/chempolicyreport.

[2] REACH establishes a fairly extensive, multi-step process by which chemicals are to be identified and added to the candidate list. See REACH Article 59. The initial version of the official candidate list is available at echa.europa.eu/chem_data/candidate_list_table_en.asp.

[3] This intent is also one of the stated objectives of REACH; see REACH Preamble Recitals 12 and 70 and Article 55.

[4] See REACH Article 57.

[5] Chemicals meeting the criteria for classification in category 1 or 2 in accordance with EU Directive 67/548/EEC on Classification and Labelling of Dangerous Substances, available at eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31967L0548:EN:NOT.

[6] Chemicals meeting the PBT or vPvB criteria in Annex XIII of the REACH Regulation.

[7] See REACH, Article 57(f). EU's prioritization list of potential endocrine disrupting chemicals is available at ec.europa.eu/environment/endocrine/index_en.htm.

[8] See echa.europa.eu/doc/press/pr_08_18_pub_consultations_20080630.pdf.

[9] See echa.europa.eu/consultations/authorisation/svhc/svhc_cons_en.asp.

[10] CMRs are listed in Annex I to Directive 67/548/EEC on Classification and Labelling of Dangerous Substances, available at ecb.jrc.it/esis/index.php?PGM=cla. PBTs and vPvBs have been identified by a PBT working group under the European Chemicals Bureau; see ecb.jrc.it/esis/index.php?PGM=pbt.

[11] In Annex I, more than 800 chemicals have been designated as Category 1 (known) or Category 2 (likely) carcinogens, about 175 as category 2 mutagens and about 85 as Category 1 or Category 2 reproductive toxicants. A significant number of the substances on some of these lists may be exempt from REACH authorization, because they qualify either as fuels or pesticides; see REACH Article 56(4) and ChemSec's description of the methodology used to derive the SIN List, available at www.chemsec.org/documents/080917_SIN_List_methodology.pdf. The PBT working group has designated about 25 chemicals as PBT/vPvBs. The European Commission has identified 194 likely endocrine disruptors and 125 potential endocrine disruptors. See ec.europa.eu/environment/endocrine/index_en.htm.

[12] The SIN List and an explanation of its purpose and origins are available at www.chemsec.org/list.

[13] The CMRs, PBTs, vPvBs and endocrine disruptors ChemSec included on the SIN List are only a subset of the chemicals so designated by the EU; see endnote 11. To identify additional chemicals of equivalent concern, ChemSec applied the guidance that ECHA has developed to identify SVHCs based on equivalent concern; see Section 3.3.3 of the guidance available at reach.jrc.it/docs/guidance_document/svhc_en.pdf. For more information about ChemSec's process, see www.chemsec.org/list. Environmental Defense Fund has not independently evaluated the available data for SIN List chemicals or the decision to add them to the list.

[14] This count reflects the replacement of the seven SIN List CAS numbers for asbestos with the CAS number for asbestos that appears on the TSCA Inventory, 1332-21-4; see Appendix 2.

[15] Tables 1-4 are provided in a separate file, available along with this report at www.edf.org/AcrossThePond.

[16] The identities of about 15,000 chemicals on the TSCA Inventory are confidential and hence are not included in the public version. U.S. Environmental Protection Agency, "Inventory Comparison Project: Facts related to the TSCA Inventory." Office of Pollution Prevention and Toxics, Washington, DC. Draft dated 8/15/05.

[17] See www.epa.gov/oppt/iur/pubs/basic-information.htm.

[18] These groups include polymers, microorganisms, naturally occurring chemical substances, and certain forms of natural gas. In addition, reporting exemptions apply to chemicals that are: a) produced in small quantities for research and development; b) imported as part of an article; c) manufactured as an impurity, byproduct (under certain circumstances), or non-isolated intermediate; and d) manufactured by persons who qualify as small manufacturers. Several additional categories of chemicals are granted partial reporting exemptions. See www.epa.gov/oppt/iur/pubs/guidance_qanda.pdf.

[19] The identities of more than 1,300 chemicals reported under the IUR in 2002 were confidential and hence are not included in the public version. Personal communication to Environmental Defense Fund from EPA, September 2005. Analogous data for 2006 are not available but are expected to be similar.

[20] See U.S. EPA, National Pollution Prevention and Toxics Advisory Committee (NPPTAC), Broader Issues Work Group, "Initial Thought-Starter: How can EPA more efficiently identify potential risks and facilitate risk reduction decisions for non-HPV existing chemicals?" Draft dated October 6, 2005, pp. 3-4, at www.epa.gov/oppt/npptac/pubs/finaldraftnonhpvpaper051006.pdf; and Environmental Defense comments on Proposed Rule, TSCA Inventory Update Reporting Revisions (70 *Fed. Reg.* 3658, 26 January 2005), Docket ID No. EPA-HQ-OPPT-2004-0106, accessible at www.regulations.gov (search for docket number).

[21] This count includes hexabromocyclododecane, which is reported under the IUR using two CAS numbers—25637-99-4 and 3194-55-6—which are identified by EPA as corresponding to the same substance; see www.epa.gov/hpvis/rbp/HBCD.3194556.Web.RBP.31308.pdf. According to EPA: "There are two CAS numbers for HBCD: 1,2,5,6,9,10 hexabromocyclododecane (CAS 3194-55-6) is an HPV chemical that was manufactured or imported in the U.S. between 10 and 50 million pounds in 2005. Hexabromocyclododecane (CAS 25637-99-4) is a moderate production volume (MPV) chemical manufactured or imported between 10 thousand and 500 thousand pounds in 2005." In our tally we used the volume data reported for CAS# 3194-55-6.

[22] This breakdown of companies adds up to more than the total number of companies because some companies manufacture, import or make CBI claims regarding the same or different chemicals.

[23] Tables 1-4 are provided in a separate file, available along with this report at www.edf.org/AcrossThePond.

[24] Tables 1-4 are provided in a separate file, available along with this report at www.edf.org/AcrossThePond.

[25] Tables 1-4 are provided in a separate file, available along with this report at www.edf.org/AcrossThePond.

[26] The SIN List's CMRs are all listed in Annex I to Directive 67/548/EEC on Classification and Labelling of Dangerous Substances, available at ecb.jrc.it/esis/index.php?PGM=cla. The SIN List's PBTs and vPvBs have been identified by a PBT working group under the European Chemicals Bureau; see ecb.jrc.it/esis/index.php?PGM=pbt.

[27] EU's prioritization list of potential endocrine disrupting chemicals is available at ec.europa.eu/environment/endocrine/index_en.htm.

[28] EPA has used its TSCA Section 4 authority to issue test rules for about 140 chemicals. For about 60 additional chemicals, EPA has obtained data through Section 4 Enforceable Consent Agreements (ECAs), which it uses as an alternative to test rules in cases where there is agreement with industry on the need for, and scope of, testing. See U.S. Environmental Protection Agency, *Overview: Office of Pollution Prevention and Toxics Programs*, January 2007, prepared by OPPT for the National Pollution Prevention and Toxics Advisory Committee, p. 4, available at www.epa.gov/oppt/pubs/oppt101c2.pdf.

[29] EPA's HPV Challenge web site is at www.epa.gov/chemrtk/index.htm. For more information on the HPV Challenge, its status and what it has and has not achieved, see Environmental Defense Fund's report *High Hopes, Low Marks*, available at www.edf.org/hpvreportcard.

[30] According to OECD: "The SIDS is regarded as the minimum information needed to assess an HPV chemical to determine whether any further work should be carried out or not." See www.oecd.org/document/21/0,3343,en_2649_34379_1939669_1_1_1_1,00.html.

[31] Source: Environmental Defense Fund analysis of EPA's hazard characterizations of HPV Challenge chemicals posted through September 2008 at iaspub.epa.gov/oppthpv/hpv_hc_characterization.get_report?doctype=2. Details are available upon request.

[32] Twelve of the 14, including eight of the nine with final OECD assessments, and four of the five without, are on the TSCA Inventory.

[33] Government Accountability Office, Report GAO-05-458, *Chemical Regulation—Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, 2005, p. 58, available at www.gao.gov/new.items/d061032t.pdf.

[34] See www.epa.gov/opptintr/newchems/pubs/cnosnurs.htm.

[35] See, for example, this Canadian government factsheet on nonylphenol (NP) and nonylphenol ethoxylates (NPEs): www.ec.gc.ca/CEPARegistry/subs_list/NPE_BG.cfm. Canada's assessment also found "that Octylphenol (OP) and its Ethoxylates (OPEs) have similar toxicological properties and possibly greater estrogenic properties than NP and NPEs." See canadagazette.gc.ca/partI/2004/20041204/html/notice-e.html#i5.

[36] Some of the observed changes may reflect changes in the confidential business information (CBI) status of specific chemicals. The identities of many chemicals on the TSCA Inventory and reported under the IUR are claimed CBI and hence are not revealed to the public; see endnotes 16 and 19. Companies may have changed their CBI designations between the two cycles, or a different mix of companies may have reported the same chemical.
[37] See solutions.3m.com/wps/portal/3M/en_US/PFOS/PFOA/.
[38] See www.epa.gov/oppt/pbde/.
[39] This chemical is Poly(oxy-1,2-ethanediyl), alpha-(nonylphenyl)-omega-hydroxy-, branched, CAS# 68412-54-4. See endnote 18 and associated text for more on polymers and other classes of chemicals exempted from IUR reporting.
[40] The author has inquired with EPA as to why so many HPV chemicals, including those SIN List chemicals reported here, appear to have disappeared between the 2002 and 2006 reporting cycles. It is of course possible that the reported volume did change dramatically. EPA's infrequent reporting system (once every four years, recently extended to once every five years), which also entails reporting of only a single year's production or import, may well miss real fluctuations in the year-to-year volumes of specific chemicals; see endnote 20 and associated text.
[41] The TSCA Inventory also has four other related listings for asbestos, none of which match the SIN List CAS numbers: CAS# 68526-78-3 Asbestos, reaction products with silica and triethoxyoctylsilane; 69278-68-8 Asbestos, reaction products with tert-butylphenol-formaldehyde polymer; 71011-15-9 Asbestos, reaction products with triethoxyoctylsilane; and 72623-76-8 Asbestos, reaction products with calcium oxide and silica.
[42] For one SIN List chemical, Hexabromocyclododecane, we did all searches in our analysis using two CAS numbers: 25637-99-4, which is that used on the SIN List; and 3194-55-6, which is identified by EPA as corresponding to the same substance. See www.epa.gov/hpvis/rbp/HBCD.3194556.Web.RBP.31308.pdf.
[43] We purchased the July 2008 version of the TSCA Inventory on a CD-ROM from the National Technical Information Service (NTIS), available at www.ntis.gov/products/tscatrack.aspx.
[44] See www.epa.gov/oppt/iur.
[45] See www.epa.gov/oppt/chemtest/pubs/sumindex.htm.
[46] The Section 12(b) list is posted at www.epa.gov/oppt/import-export/pubs/12blist.htm, and is indicated to be current as of February 29, 2008.
[47] See www.epa.gov/oppt/chemtest/pubs/sunset.htm.
[48] See www.edf.org/hpvtracker. Data were current through June 30, 2008.
[49] EPA's HPV Challenge web site is at www.epa.gov/chemrtk/index.htm; the data we used were current through June 30, 2008. The Organization for Economic Cooperation and Development (OECD) operates a sister voluntary HPV data development program. The OECD HPV database is at cs3-hq.oecd.org/scripts/hpv/; the data we used were current as of August 12, 2008.
[50] As previously noted, asbestos is listed on the TSCA Inventory as CAS# 1332-21-4 but not as any of the seven CAS numbers listed on the SIN List for various forms of asbestos. In Table 1 we flagged all seven of these CAS numbers as being subject to Section 6 regulation. The TSCA Inventory also has four other related listings for asbestos, none of which match the SIN List CAS numbers: CAS# 68526-78-3 Asbestos, reaction products with silica and triethoxyoctylsilane; 69278-68-8 Asbestos, reaction products with tert-butylphenol-formaldehyde polymer; 71011-15-9 Asbestos, reaction products with triethoxyoctylsilane; and 72623-76-8 Asbestos, reaction products with calcium oxide and silica.
[51] A total of 14 SIN List CAS numbers contain chromium, all but one of which appear on the TSCA Inventory, but only five of these carry flags indicating Section 6 regulation. EPA's regulation covers only *hexavalent* chromium compounds, and only the subset of those that can be used for water treatment in water cooling systems. Presumably most or all of the nine unflagged CAS numbers either do not contain the hexavalent form of chromium or are not used as water treatment chemicals. It is also possible that differences between EU and U.S. lists in CAS numbers for these chemicals accounts for some of the unflagged CAS numbers.

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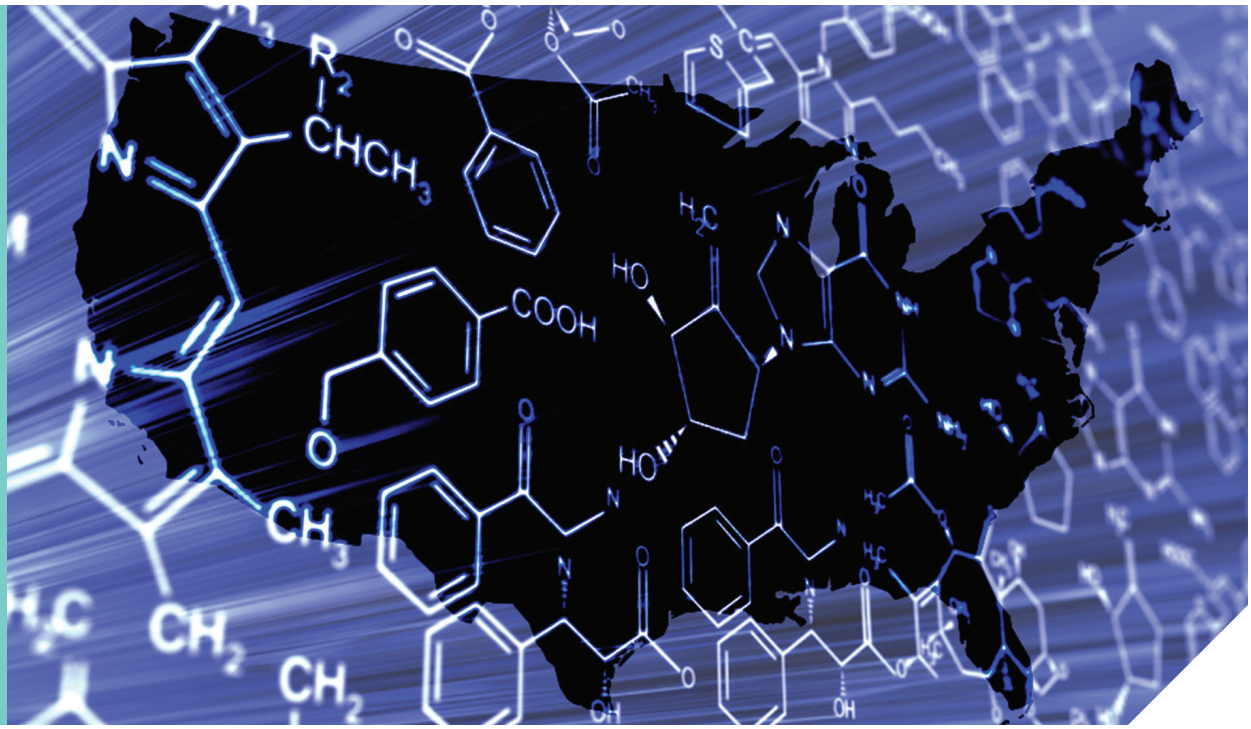

Toxics Across America

Who Makes the Billions of Pounds of Toxic Chemicals Flowing Through the U.S. Economy Each Year

Addendum 122

Toxics Across America

Who Makes the Billions of Pounds of Toxic Chemicals Flowing Through the U.S. Economy Each Year

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Cover photo: iStock

The complete report is available online at edf.org/health/ToxicsAcrossAmerica.

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(in separate document available at: edf.org/health/ToxicsAcrossAmericaAppendices.pdf)

Executive summary

Over the past decade, efforts to identify and manage the risks of hazardous chemicals have been ramping up in the United States at the state and federal level, and internationally, most notably in Canada and the European Union (EU). A primary starting point for these efforts is the identification of chemicals that warrant scrutiny or action due to their potential to cause harm to human health or the environment. Several states in the U.S., the U.S. Environmental Protection Agency (EPA), and the EU Chemicals Agency, have developed authoritative lists of chemicals of concern, based on credible scientific evidence of hazard, alongside exposure data where available. The use of these lists by the authoritative bodies ranges from simply the identification of such chemicals, to required disclosure, labelling or warnings for products that contain them, to restrictions or prohibitions on the use of such chemicals in the market.

These lists of hazardous chemicals identified by U.S. and EU authoritative bodies served as the basis for a list of priority chemicals developed for the "Mind the Store" campaign (hereafter the "MTS List chemicals") launched by the Safer Chemicals Healthy Families coalition. That campaign asks the nation's top retailers to identify and take action to address products they sell that contain any of the listed chemicals.

This report aims to better elucidate the extent to which such hazardous chemicals are in commerce in the U.S., critical to any effort to identify and manage their risks. The report identifies and analyzes available information on the production, import and use of MTS List chemicals drawn from the 2012 reporting cycle of EPA's Chemical Data Reporting (CDR) program. More specifically, the report identifies those companies that reported making or importing MTS List chemicals, in what amounts, at what locations and for what consumer or commercial uses.

The analysis presented in this report supports the following findings:

- Most MTS List chemicals are in active commerce in the U.S.: At least **92%** of the MTS List chemicals appear on the U.S. TSCA Inventory. At least **60%** of the MTS List chemicals were reported as produced or imported in quantities exceeding **25,000 pounds** in 2011 (the most recent year for which EPA has collected data).

- At least **81 MTS List chemicals** are produced or imported annually in amounts of **1 million or more pounds**. At least **14** exceed **1 billion pounds** annually, including carcinogens such as formaldehyde and benzene and the endocrine disruptor bisphenol A (BPA).

- At least **329 companies** are producing or importing MTS List chemicals in the U.S.

- Some companies are associated with multiple MTS List chemicals—as many as **24 per company. BASF** and **Dow Chemical** reported producing or importing 24 and 23 MTS List chemicals, respectively.

- Many MTS List chemicals are produced or imported by multiple companies at numerous sites—as many as **47 companies at 73 separate sites per chemical**.

- MTS List chemicals are produced or imported in **45 states** as well as the Virgin Islands, at as many as **91 sites per state**. Companies with sites in **Texas**, **Pennsylvania**, **New Jersey** and **New York** reported producing or importing at least **40 MTS List chemicals**.

- The number of MTS List chemicals produced or imported per state **ranges from 1 to 46**. The number of states producing or importing a given MTS List chemical **ranges from 1 to 28**. The **carcinogenic heavy metals chromium, nickel and lead** are each produced or imported at sites located in **25 or more states**.

- At least **91 MTS List chemicals** are found in consumer and commercial products, and these chemicals are reported as used in as many as **12 different products**.

- For **78 MTS List chemicals**, manufacturers and importers do not know certain aspects of the downstream consumer and commercial uses of these chemicals.

- At least **8 MTS List chemicals** are found in children's products, including chromium, formaldehyde and the personal care product ingredient and potential endocrine disruptor, decamethylcyclopentasiloxane.

Our findings demonstrate that the production, import and use of the MTS list of hazardous chemicals in the U.S. are extensive. These chemicals are being made across the country, by many companies, often in very large amounts and for many different uses.

Additionally, our findings support the need for policies that generate information needed to improve public and market knowledge about chemical manufacture, import and use in the U.S. While EPA makes a large amount of information publicly available through the CDR program, there are many limitations to the data based on the manner by which EPA collects and disseminates the data.

Introduction

Hazardous chemicals are potential threats to human health and the environment, particularly when the nature and extent of production and use of such chemicals is not well understood and managed. This report will examine production and use information available in the U.S. for chemicals of concern identified by authoritative bodies in the U.S. and the European Union (EU), to better elucidate the potential risks they pose.

Hazardous chemicals identified by U.S. and EU authoritative bodies have been compiled into a list of priority chemicals developed for the "Mind the Store" campaign (hereafter the "MTS List chemicals") launched by the Safer Chemicals Healthy Families Coalition. These hazardous chemicals have been linked to serious chronic diseases and disorders such as:

- cancer
- developmental toxicity
- reproductive toxicity
- endocrine disruption
- dermal sensitization
- inhalation sensitization

Many of these chemicals are also persistent in the environment and able to bioaccumulate in people and other living organisms.

This report includes information reported to EPA in 2012 on:
- **130 MTS List chemicals,**
- **submitted by 329 companies,**
- **for production or import at 632 sites.**

This report identifies and analyzes available information on the production, import and use of MTS List chemicals reported by chemical manufacturers and importers to the U.S. EPA in 2012 under its periodic Chemical Data Reporting (CDR) system. The report identifies which of these hazardous chemicals are in commerce in the U.S., in what amounts they are being made, which companies are producing them and where they are being produced. The data are presented by chemical, by company, and by state.

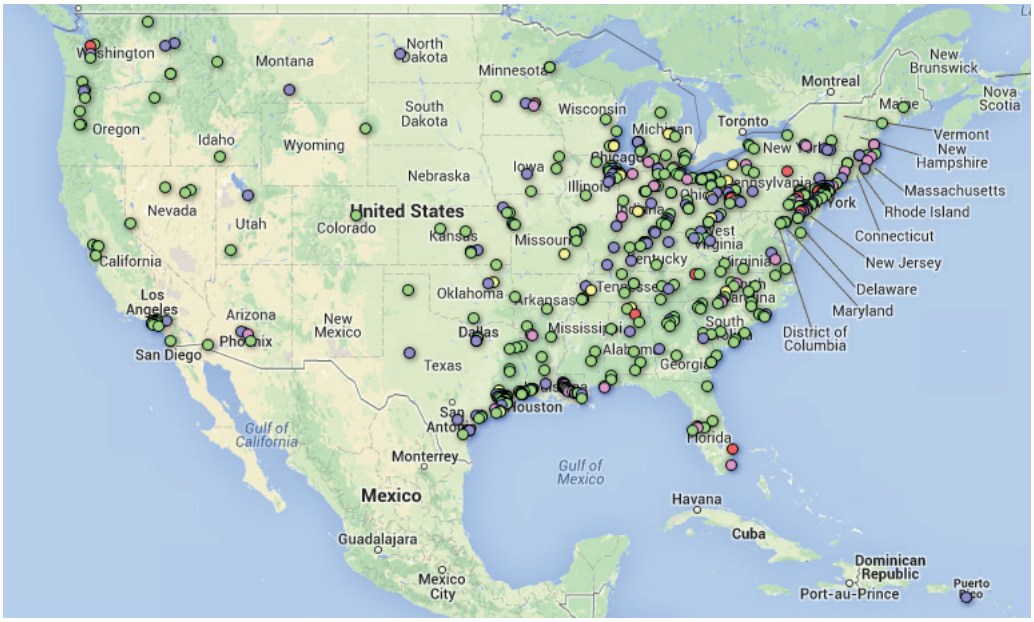
In addition, this report examines the available data on consumer and commercial uses reported by the producers and importers of these hazardous chemicals and whether they were reported to be present in children's products. However, the report also demonstrates the limited extent to which such downstream use information is known to or reasonably ascertainable by the manufacturers and importers of these chemicals. This finding highlights the need to collect use information directly from processors and end users of these chemicals.

The production and use data for the MTS List chemicals provided in this report are limited to the information reported to EPA and not claimed by reporting companies as "confidential business information" (CBI). By law, EPA cannot share CBI with the public. Therefore, the information on hazardous chemicals presented in this report represents only a partial picture of the production and use of these chemicals in the U.S.

Despite the limitations to the information available on these hazardous chemicals, our aim is to make these data as accessible and useful to the public as possible. The report is accompanied by a separate interactive, searchable map of the U.S., which provides direct access to the available production and use data on specific chemicals in a geographically targeted manner. Figure 1 (see page 2) is an image of that map showing sites of production or import of the MTS List chemicals.

FIGURE 1

Where MTS List chemicals are made or imported in the U.S.



Map data ©2014 Basarsoft, Google, INEGI, Inav/Geosistemas SRL, Orio, ME

An image from the interactive, searchable map of the U.S., showing sites of production or import of the MTS List chemicals. One additional site in Hawaii is not shown. The dot colors reflect the number of MTS List chemicals reported at each site. To access the interactive map and search it for a specific company, chemical, or location, go to edf.org/health/ToxicsAcrossAmericaMap.

Together, we hope the report and the map provide the public and consumers with a much clearer picture of the extent of production and use of certain hazardous chemicals in U.S. commerce, with the aim of increasing public engagement in supporting public policy and private-sector efforts to reduce the use of and exposure to hazardous chemicals.

Data sources used

The list of hazardous chemicals used in this report was developed by the Safer Chemicals Healthy Families coalition. In April 2013, the coalition launched the "Mind the Store" Campaign, asking the top 10 retailers in the nation to identify and take action to address products they sell that contain any of a list of toxic chemicals the Campaign dubbed the "Hazardous Hundred+ List of Chemicals of High Concern," which we refer to in this report as "MTS List chemicals."

The MTS list consists of chemicals that have been linked to cancer, developmental toxicity, reproductive toxicity, endocrine disruption, or dermal or inhalation sensitization, some of which are also persistent and bioaccumulative. The list is comprised of two sublists. The first includes chemicals of high concern identified by at least two governmental authorities in the U.S. and the EU.[1] The second, supplemental list is a non-exhaustive set of chemicals identified on the basis that they pose concerns similar to the chemicals on the first list, but which do not appear on at least two of the authoritative lists.[2]

We chose to use the MTS List for this report because it was developed using a consistent and systematic approach to narrow the large number of chemicals on some authoritative lists to focus on those appearing on more than one list, as well as closely related chemicals expected to pose similar concerns. Environmental Defense Fund (EDF) was centrally involved in the development of the chemicals list for the "Mind the Store" Campaign.

The production, processing and use data used in this report were collected and disseminated by the U.S. EPA under its Chemical Data Reporting (CDR) rule, established under the authority of the Toxic Substances Control Act (TSCA).[3] Under the CDR, the EPA periodically collects manufacturing, processing and use data from companies for qualifying chemicals found on the TSCA inventory that they produce domestically or import.[4] The data used in this report were collected during the 2012 submission period, and cover production or import in 2011.[5] Our analysis examines the subset of data reported under the CDR for chemicals on the MTS List, which includes:

- information on 130 MTS List chemicals,
- submitted by 329 companies,
- for production or import at 632 sites.

At the end of this report, the "How we did our analysis" section describes in more detail how we used the MTS List and data collected under the CDR in conducting our analysis.

Questions considered

The EPA's CDR data identify many, though by no means all, of the chemicals in commerce in the U.S. This report targets a further subset of those chemicals—those MTS List chemicals reported under the CDR—as a means to elucidate the extent of production and use of hazardous chemicals in U.S. commerce. We explore the following questions:

- **Which of the MTS List chemicals are in commerce in the U.S.?**
- **In what amounts are these chemicals produced or imported in the U.S.?**
- **Which companies produce or import MTS List chemicals in the U.S.?**
- **In which states are MTS List chemicals produced or imported?**
- **What are the consumer and commercial uses of the MTS chemicals known to or reasonably ascertainable by their producers and importers?**
- **Which MTS List chemicals are reported to be used in children's products?**

Limitations to our analysis

Our analysis is based on the latest publicly available information reported to and provided by EPA under the CDR (see "How we did our analysis" for details). Unfortunately, our reliance on this information constrains several aspects of our analysis. The main limitations are the following:

- The most recent public data on U.S. chemical production and import were collected by EPA in 2012 for activity during the calendar year 2011. Given the dynamic nature of the chemical market, **some of the data we report here on chemicals, their production/import volumes and their associated companies may have changed**.

- Any chemical produced or imported in the U.S. in an amount below 25,000 pounds in 2011 at a given site was not required to be reported at all. Other exemptions from CDR reporting (e.g., for small businesses, for certain polymers) also mean that certain chemicals that are in active commerce were not reported. Hence, EPA's data and our analysis do not include information on any MTS chemical that was produced or imported at lower volumes or was exempt from reporting.

- Manufacturers and importers were only required to report processing- and use-related information for chemicals produced or imported at 100,000 pounds or more per site in 2011; therefore, these types of data are unavailable for many of the reported MTS List chemicals.

- For processing- and use-related information, the 2012 CDR only requires that companies report such information to the extent it is "known to or reasonably ascertainable by" them. This limits the reporting obligation to "all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know."[6] Submitters are not required to take steps such as conducting customer surveys to fill in data gaps. Because chemical makers frequently have only limited knowledge of the ways their chemicals are used or processed by their customers, the CDR provides only a partial picture of the processing and use of reported chemicals.

- Under TSCA, U.S. companies have wide latitude to claim information they report to EPA as confidential business information (CBI). EPA rarely challenges such claims and must not publicly disclose information claimed as CBI. In recent years, EPA has taken steps to increase the amount of information released to the public.[7] One such step was to require upfront substantiation on the 2012 CDR reporting for all CBI claims pertaining to processing- and use-related information, and to chemical site and chemical identity.[8] This step has substantially reduced the number of such claims made relative to earlier reporting cycles. However, the specific identities of thousands of chemicals are not included in the public version of the TSCA Inventory because their producers have claimed those chemical identities to be CBI, resulting in the masking of 451(6%) chemical identities in the CDR data.[9] Similarly, companies can also hide their own identities by claiming their production or import of a chemical to be CBI. **Hence, the chemicals and companies we list in this report represent only the subset that are not claimed CBI.** Our report includes data on the extent to which specific types of CDR information were claimed CBI for MTS List chemicals.

It is important to bear these limitations in mind when reading this report.

Analysis

1. Which MTS List chemicals are in commerce in the U.S.?

FINDING **Most MTS List chemicals are in active commerce in the U.S.:**

- **At least 92% of the MTS List chemicals appear on the U.S. TSCA Inventory.**
- **At least 60% of the MTS List chemicals were reported as produced or imported in quantities exceeding 25,000 pounds in 2011 (the most recent year for which EPA has collected data).**

DETAILS Our analysis utilized 216 distinct Chemical Abstract Service Registry numbers (CAS numbers) to represent the 120 MTS List chemicals and chemical categories (see "How we did our analysis" for details). Of these 216 CAS numbers, 199 (92%) appear on the latest (January 2014) public version of the U.S. TSCA Inventory. A list of these CAS numbers is provided in Appendix 1.[10] The TSCA Inventory is a cumulative list of all chemicals that have been in U.S. commerce at some time since the Inventory was developed in 1979.

This figure is likely an underestimate of the number of MTS List chemicals that are or have been in commerce in the U.S. because:

- Certain types and uses of chemicals are exempted from TSCA and hence those chemicals would not have been reported at the time the Inventory was established.
- The identities of many chemicals on the TSCA Inventory are claimed confidential and hence do not appear on the public version.[11]

On the other hand, a number of the MTS List chemicals may no longer or not currently be in commerce in the U.S. Because it is a cumulative listing over time, the TSCA Inventory contains an unknown but likely significant number of chemicals no longer in active production or use.

Unfortunately, EPA identifies chemicals active in commerce only infrequently and in a partial manner. Companies are required to report, once every four years, information on each non-exempt chemical substance on the TSCA Inventory they produce or import in annual amounts of 25,000 pounds or more per site. In 2012, full reporting of manufacturing data was required only for 2011, while reporting of production volume data was also required for 2010. Starting in 2016, the CDR will include a greater amount of production volume information. Companies triggering the reporting threshold of 25,000 pounds or more per site for any year since the last principal reporting year will be required to report production volume for *all* years since the last principal reporting year.[12]

Based on the most recent publicly available CDR data, collected in 2012, 130 (60%) of the 216 MTS List CAS numbers were reported as produced or imported in 2011 above the CDR threshold of 25,000 pounds per site. See Appendix 1.

The 60% figure is likely an underestimate of the number of MTS List chemicals in active commerce in the U.S. because:

- It is very likely that some of the MTS List chemicals are produced or imported in amounts below the 25,000 pound reporting threshold. In general, the number of chemicals produced or imported in smaller volumes is greater than the number produced in large volumes.
- Some categories of chemicals and companies are exempted from CDR reporting.[13]
- The identities of chemicals claimed confidential do not appear on the public version of the CDR database.[14]

Changes in production volume since 2011 may also influence the accuracy of our count. Some chemicals below the reporting threshold in 2011 may now be above it, and vice versa. Extensive fluctuations have been documented in which chemicals are reported from one reporting cycle to the next.[15]

2. In what amounts are MTS List chemicals produced or imported in the U.S.?

FINDING **Many MTS List chemicals are produced or imported in substantial quantities in the U.S. At least 81 MTS List chemicals exceed one million pounds annually. At least 14 exceed one billion pounds annually, including carcinogens such as formaldehyde and benzene and the endocrine disruptor bisphenol A (BPA).**

DETAILS Under the CDR, EPA requires companies to report the quantity of each chemical they produced or imported whenever those amounts exceed the reporting threshold. In general, EPA provides the individual non-CBI production volumes by site as well as an aggregate production volume for that chemical, summed up across all reporting producers and importers.[16]

Of the 130 MTS List CAS numbers reported in the CDR, 81 (62%) are produced or imported in excess of one million pounds annually, aggregated across all reporters and sites. And 14 of these 81 high production volume chemicals are produced or imported in amounts above a staggering *one billion* pounds annually.

There are limitations to the available production volume information, by site and also within the aggregated data. Reported volumes may be claimed as confidential business information (CBI). For many CDR chemicals there are multiple reporting sites and companies; in disseminating aggregate production volume by chemical, EPA generally sums up the reported volumes across all producers and importers. If most or all of the individual production volumes for a given chemical are claimed CBI, however, the aggregate production data are assigned to and reported as a range in order to protect CBI. Additionally, EPA has in some cases masked certain individual production volumes in order to be able to provide aggregate volume data fora given chemical while still protecting CBI. In a few cases, EPA withheld aggregate production volume for a specific substance to protect individual production volume data claimed as CBI.

See Appendix 1 for aggregate production volumes by chemical and Appendix 2 for individual companies' production volumes.

For the 199 MTS List CAS numbers on the TSCA Inventory, Appendix 1 displays either a specific aggregated production volume or the aggregate volume range reported by EPA. These can in turn be assigned to EPA's even broader volume classifications of high-, medium- and low-production volume (HPV, MPV and LPV, respectively). Two other broad categories are required to capture all of the CAS numbers, due to CBI claims made for some production volume data:

- First, a category we have named "≥Medium" is used to cover chemicals for which aggregate data are withheld, but certain individual production volume data are available and sufficient to determine that the aggregate volume is at least 25,000 lbs/year, which is the lower bound

used to define MPV chemicals. Non-CBI data from individual companies are insufficient in these cases, however, to determine whether or not these chemicals are produced at or above one million lbs/year, which defines HPV chemicals; therefore we have categorized them as "≥Medium."

- Second, a "CBI" category covers instances where all of the submissions for a given chemical claimed production volume CBI and as a result EPA withheld the aggregate production volume.

The breakdown of MTS CAS numbers on the TSCA inventory across aggregate production volume categories and claimed CBI is presented in Table 1.

TABLE 1

MTS List chemicals categorized by aggregate production volume

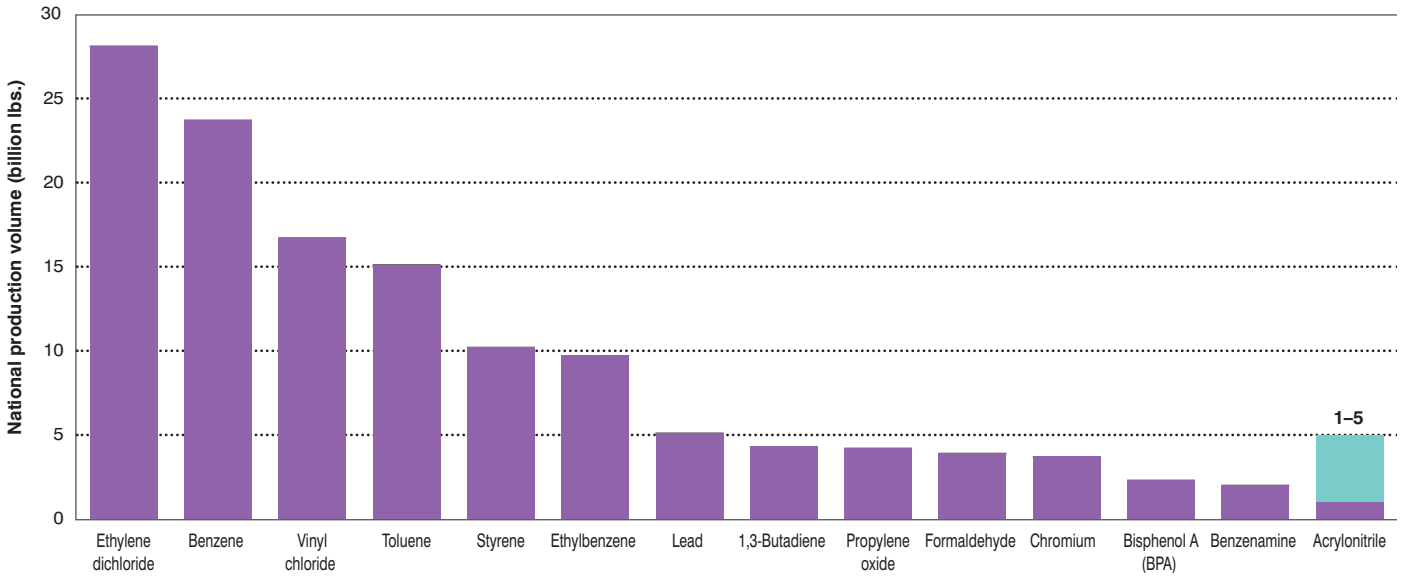
Production volume category	Aggregate volume (lbs./yr)	# of CAS numbers	% of total
High	> 1million	81[17]	41%
≥Medium	≥25,000	6	3%
Medium	25,000-1 million	18	9%
Low	<25,000	69	35%
CBI	Withheld	25	13%

Note that, because chemicals produced at levels below 25,000 pounds per year per site are not required to be reported under the CDR, we cannot distinguish between MTS List chemicals on the inventory that are in commerce but at levels <25,000 pounds per year per site and those that are not in active commerce in the U.S.

As noted above and in Figure 2, 14 of the MTS List chemicals are produced and imported in the U.S. in huge quantities, exceeding one *billion* pounds annually.

FIGURE 2

MTS List chemicals reported at >1 billion lbs in 2011



3. Which companies produce or import MTS List chemicals in the U.S.?

FINDING **At least 329 companies are producing or importing MTS List chemicals in the U.S. Some companies are associated with multiple MTS List chemicals—as many as 24 per company. BASF and Dow Chemical reported producing or importing 24 and 23 MTS List chemicals, respectively. Many MTS List chemicals are produced or imported by multiple companies at numerous sites—as many as 47 companies at 73 separate sites per chemical.**

DETAILS A total of 329 companies reported producing or importing one or more MTS List chemicals in the U.S. in 2011. Of these, 168 companies reported producing such chemicals, while 240 reported importing them. Twenty-nine companies claimed as CBI whether they manufactured or imported one or more MTS List chemicals.[18]

Across the 329 companies, the number of MTS List CAS numbers publicly reported per company varied from 1 to 24. The 14 companies reporting the most (eight or more) MTS List CAS numbers are presented in Table 2. In addition, Table 2 shows the number of MTS List CAS numbers that these companies reported manufacturing (MFR) or importing (IMP) or claimed as CBI whether they manufactured or imported them.

TABLE 2

Companies reporting the most MTS List chemicals

		# of MTS List chemicals		
	Total number of MTS List chemicals reported*	# MFR	# IMP	# CBI
BASF	24	15	18	0
Dow Chemical	23	18	13	0
Lanxess	12	6	6	2
Du Pont	12	3	9	0
Solvchem	10	2	9	0
ICC Industries	10	9	1	0
OM Group	9	7	4	0
Umicore USA	8	1	7	0
Shin Etsu	8	6	5	0
Lyondell Chemical Co	8	6	2	0
Koch Industries	8	6	3	0
Eastman Chemical	8	1	0	7
Albemarle	8	6	0	2
3M	8	5	5	0

*Numbers do not necessarily add to total because a given chemical may be produced and imported and/or claimed CBI by the same company.

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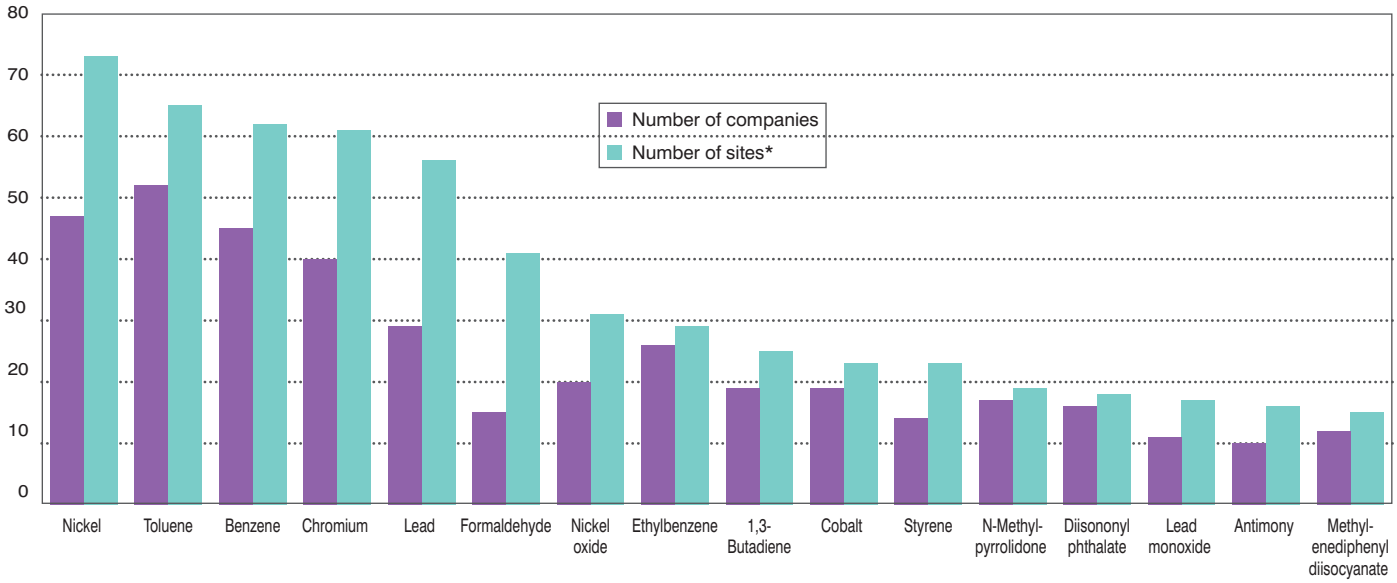
FIGURE 3

MTS List chemicals reported at the most sites



*The counts of sites per chemical include sites that have been claimed CBI.

Appendix 2 provides a full list of all companies reporting producing or importing MTS List CAS numbers in 2011.[19]

One or more companies publicly reported producing or importing all but two of the 130 CAS numbers on the MTS List that were reported under the CDR data.[20] For those two chemicals, the company or companies producing or importing them evidently opted to hide their identities by claiming their association with the chemicals confidential.

For other MTS List chemicals, companies in addition to those we have identified may produce or import them, but cannot be included because they chose to mask their identities. Finally, it is likely that companies (either those shown in Appendix 2 or other companies not listed) produced or imported MTS List chemicals, but cannot be identified because their production or import fell below the reporting threshold or they qualified for a reporting exemption.

In summary, this analysis demonstrates that a large number of companies are involved in production or import of MTS List chemicals in the U.S. Some companies are associated with many MTS List chemicals.

Similarly, many MTS List chemicals are produced or imported in the U.S. by multiple companies and at numerous different sites—as many as 47 companies at 73 separate sites per chemical. Figure 3 shows the 16 MTS List chemicals for which production or import was reported at the most sites (15 or more).

Once again, these numbers should be viewed as minimums; they do not reflect companies that hid their identities by claiming their association with these chemicals to be confidential, or whose activities were not required to be reported. The locations of 108 of the 632 (17%) sites across the U.S. reporting manufacture or import of a MTS List chemical were claimed as CBI.

Appendix 1 shows the number of companies manufacturing and importing each MTS List CAS number in the U.S., as well as the total number of sites involved. Additionally, Appendix 1 identifies the number of records for which site identity is claimed as CBI, by chemical.[21]

4. In which states are MTS List chemicals produced or imported?

FINDING **MTS List chemicals are produced or imported in 45 states as well as the U.S. Virgin Islands, at as many as 91 sites per state. Companies with sites in Texas, Pennsylvania, New Jersey and New York reported producing or importing at least 40 MTS List chemicals.**

The number of MTS List chemicals produced or imported per state ranges from 1 to 46. The number of states producing or importing a given MTS List chemical ranges from 1 to 28. The carcinogenic heavy metals chromium, nickel and lead are each produced or imported at sites located in 25 or more states.

DETAILS MTS List chemicals are produced or imported in at least 45 (90%) of U.S. states, as well as the Virgin Islands, typically at multiple sites within a state (as many as 91 sites per state). Multiple MTS list chemicals are produced or imported in certain states (as many as 46 different chemicals per state). Figure 4 presents the 10 states with the most MTS List chemicals, along with the number of chemicals and the number of sites of production or import for such chemicals in each of these states.

Appendix 3 shows these data for all 45 states and the Virgin Islands (VI).[22]

Some MTS List chemicals are produced or imported in many different states, as many as 28 states per chemical. Table 3 (page 11) shows the 10 MTS List chemicals produced or imported in the most states. For these chemicals, Table 3 also shows the number of states in which companies reported they manufactured (MFR), imported (IMP) or claimed as CBI whether they manufactured or imported the chemical.

As before, the numbers above should be viewed as minimums; they do not reflect companies or sites that hid their identities by claiming their association with these chemicals to be confidential, or whose activities were not required to be reported.

Appendix 4 shows all of the MTS List chemicals produced or imported in each state, along with their associated companies.[23]

FIGURE 4

States with the most reported MTS List chemicals

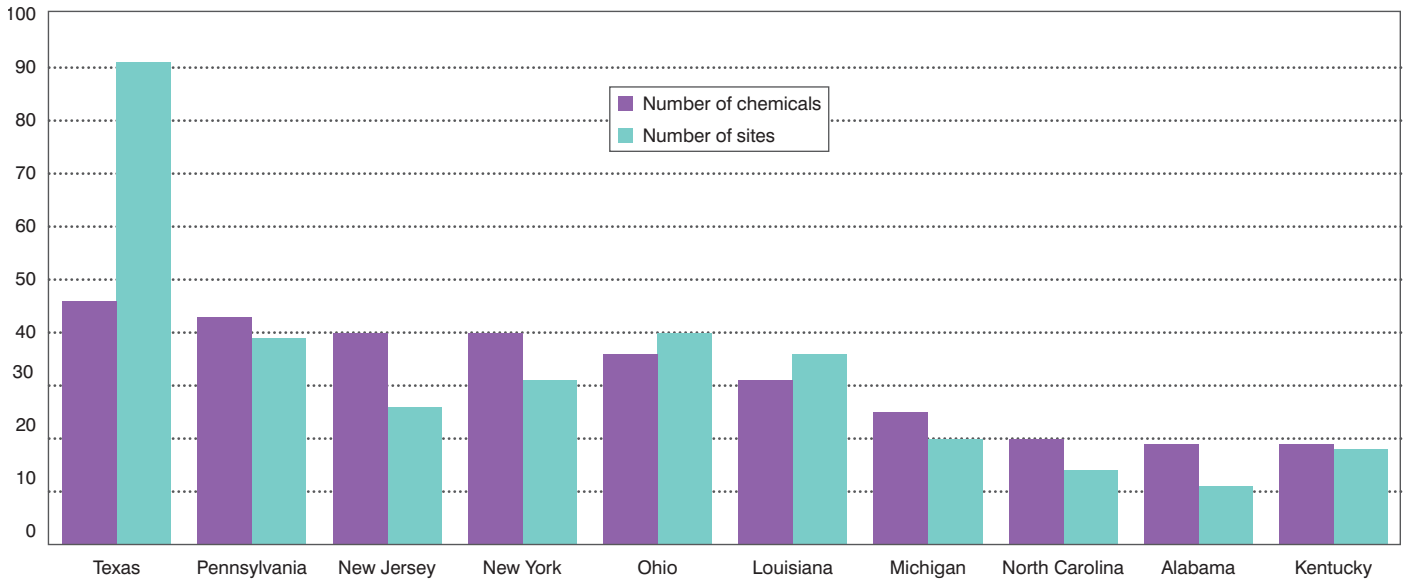


TABLE 3

MTS List chemicals reported in the most states

	Total number of states*	# of states		
		# MFR	# IMP	# CBI
Chromium	28	12	24	0
Nickel	26	14	21	2
Lead	25	22	12	1
Toluene	23	12	13	5
Formaldehyde	19	18	2	2
Benzene	18	13	8	3
Cobalt	15	4	12	3
Ethylbenzene	15	4	13	0
Nickel oxide	13	4	10	1
N-Methylpyrrolidone	13	13	7	2

*Numbers do not necessarily add to total because a given chemical may be produced and imported and/or claimed CBI in the same state or site.

5. What are the consumer and commercial uses known to or reasonably ascertainable by producers and importers of the MTS List chemicals?

FINDING **Most (at least 91) MTS List chemicals are reported to be used in consumer and commercial products. Many MTS List chemicals are associated with a variety of consumer and commercial uses, used in as many as 12 different products.**

Reported use data are limited, however, to information "known to or reasonably ascertainable by" the chemical manufacturers and importers. For 78 MTS List chemicals, manufacturers and importers do not know certain aspects of the downstream consumer and commercial uses of these chemicals.

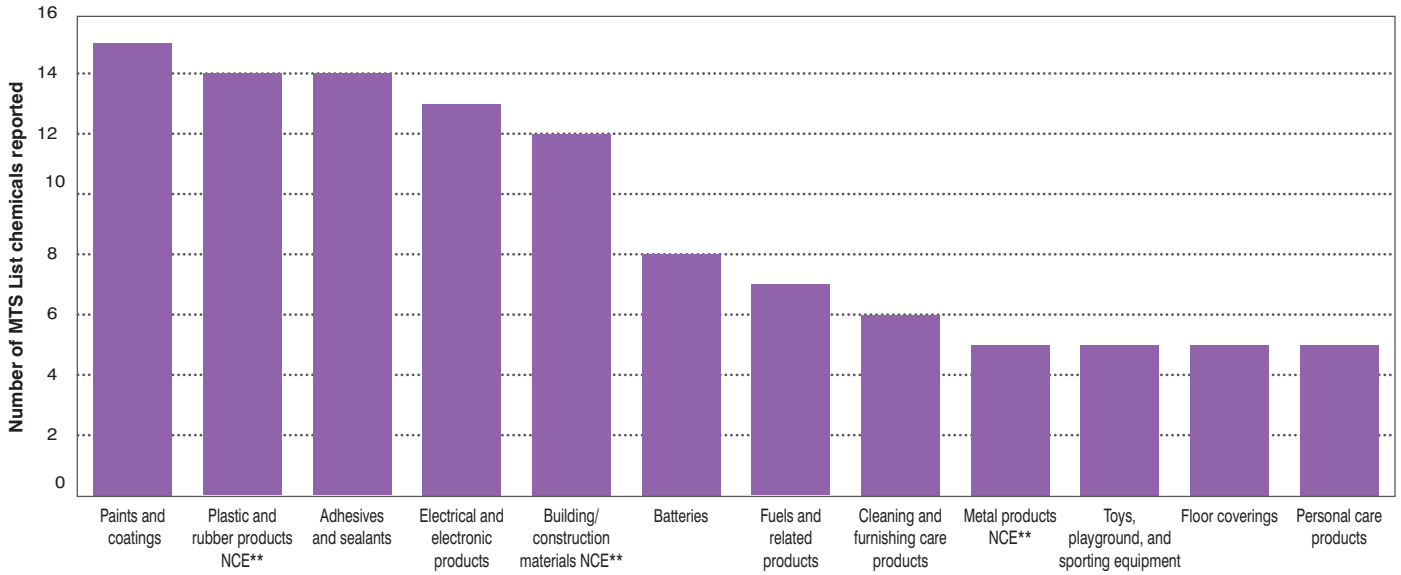
DETAILS In 2012, chemical manufacturers and importers were required to report processing and use information for chemicals they manufacture or import in amounts exceeding the reporting threshold of 100,000 pounds per site in 2011. However, these data elements may be claimed as either confidential business information (CBI) or "not known or reasonably ascertainable" (NKRA) by the manufacturer or importer.[24]

This report focuses on consumer and commercial uses reported by companies. For the purposes of the CDR, "consumer use" refers to "the use of a chemical or a mixture containing a chemical (including as part of a manufactured item, or article, such as furniture or clothing) when sold to or made available to consumers for their use."[25] "Commercial use" refers to "the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise, such as dry cleaning."[26]

Of the 130 MTS List chemicals reported on the CDR, a total of 91 (70%) are reported to have consumer and/or commercial uses. This figure is likely an underestimate of the number of

FIGURE 5

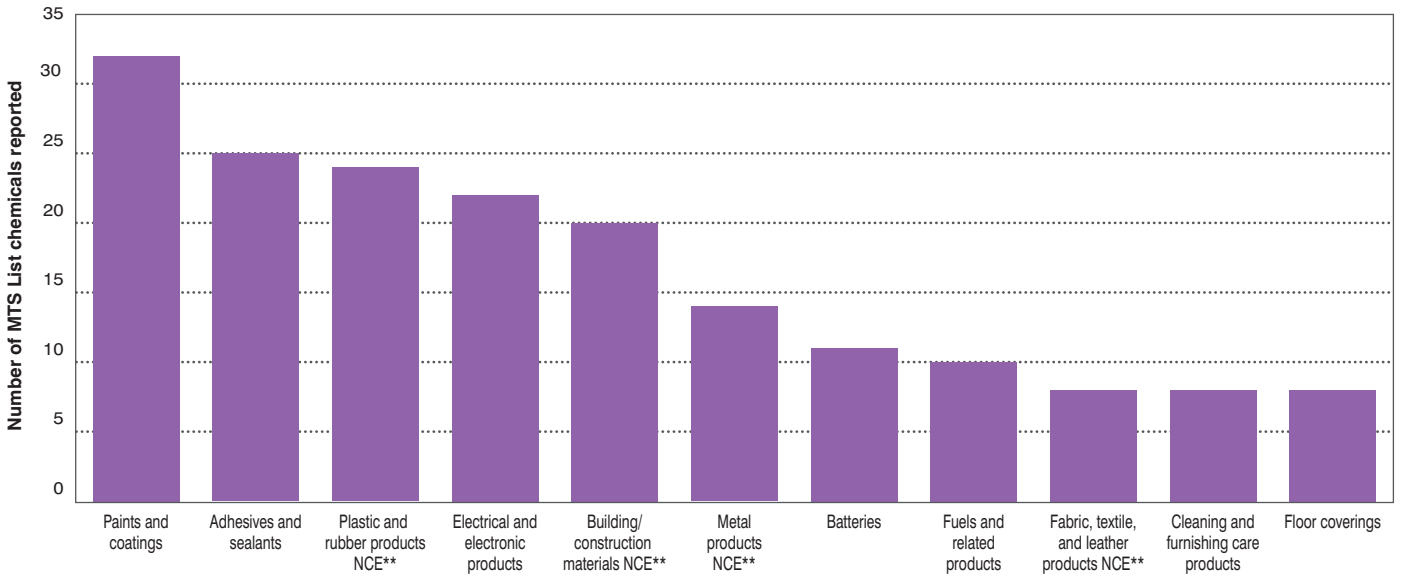
Consumer uses reported for the most MTS List chemicals*



*Does not include any uses reported as CBI, NKRA or "other (specify)"
**NCE = "not covered elsewhere"

FIGURE 6

Commercial uses reported for the most MTS List chemicals*



*Does not include any uses reported as CBI, NKRA or "other (specify)"
**NCE = "not covered elsewhere"

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MTS List chemicals that are found in consumer and commercial products, because the reporting threshold for processing and use information in the 2012 CDR reporting cycle is much higher than the reporting threshold for production volume. As noted, companies were only required to report processing and use information for chemicals manufactured or imported above 100,000 pounds per site in 2011.[27] In the next CDR reporting cycle in 2016, the reporting threshold for processing and use information will be extended to all chemicals reported under the CDR.[28]

Of the 91 CAS numbers with reported consumer or commercial uses, 83 have reported commercial uses and 54 have reported consumer uses.[29] The more frequent reporting of commercial uses for the MTS List chemicals follows the general usage trend for all chemicals reported to the CDR.[30]

"Paints and coatings" is the consumer and commercial use reported for the largest number of MTS List chemicals. The consumer and commercial uses reported for the most MTS List chemicals are presented in Figures 5 and 6 (page 12).

A total of 30 different uses were reported for the 91 MTS List chemicals with reported uses.[31] The number of uses reported for a given MTS List chemical ranges from 1–12.[32] Table 4 shows the chemicals with the greatest variety of uses, along with the most frequently reported uses for those chemicals.

Interestingly, three of the chemicals with the greatest variety of reported uses are also among the chemicals with the highest production volume: formaldehyde, ethylbenzene and benzene. These chemicals are being produced in aggregate volumes exceeding one billion pounds per year, and are also reported as used in a wide variety of products, suggesting significant potential for exposure. Five of the substances with the greatest variety of uses are phthalates, indicating their pervasive use in products.

Appendix 5 provides a list of the reported uses for all MTS chemicals having such information along with the companies that reported such information.

TABLE 4

MTS List chemicals with the greatest variety of reported uses

Chemical name	CAS #	# of uses reported*	Most commonly reported uses
Di-(C9-rich branched C8-C10-alkyl) phthalate (Part of DINP)	68515-48-0	12	Plastic and rubber products not covered elsewhere
Di-(2-ethylhexyl) phthalate (DEHP)	117-81-7	11	Plastic and rubber products not covered elsewhere
Formaldehyde	50-00-0	10	Building/construction materials—wood and engineered wood products; adhesives and sealants
Diethyl phthalate (DEP)	84-66-2	10	Adhesives and sealants; plastic and rubber products not covered elsewhere
Ethylbenzene	100-41-4	10	Paints and coatings
Diisononyl phthalate (DINP)	28553-12-0	10	Adhesives and sealants
Lead monoxide (lead oxide)	1317-36-8	9	Batteries
Di-(C10-rich branched C9-C11-alkyl) phthalate (Part of DIDP)	68515-49-1	8	Adhesives and sealants; plastic and rubber products not covered elsewhere
Benzene	71-43-2	7	Fuels and related products

*Does not include any uses reported as CBI, NKRA or "other (specify)"

6. Which MTS List chemicals are reported to be used in children's products?

FINDING **At least eight MTS List chemicals are reported as used in products intended for use by children, including chromium, formaldehyde and the personal care product ingredient and potential endocrine disruptor, decamethylcyclopentasiloxane (D5). Reported use data are limited, however, to information "known to or reasonably ascertainable by" the chemical manufacturers and importers.**

DETAILS Chemical manufacturers and importers were required to report if their chemicals are used in products intended for use by children, defined as that "the chemical or mixture is used in or on a product that is specifically intended for use by children age 14 or younger."[33] Eight MTS List chemicals were reported to be present in a product intended for use by children, some of these for more than one use. Three of the chemicals reported as used in children's products are also among the chemicals with the highest national production volume: ethylbenzene, chromium, and formaldehyde.

The chemicals reported as used in children's products and their specified uses are presented in Table 5.

Unfortunately, the reporting of MTS List chemicals used in products intended for use by children is limited to those uses known to or reasonably ascertainable by producers or importers. Of the 91 MTS List chemicals reported to have consumer and commercial uses, for 49 (54%) of them, their manufacturers or importers reported that whether they were used in products intended for children was "not known or reasonably ascertainable" at least once. That

TABLE 5

MTS List chemicals reported as used in children's products

Chemical name	CAS #	Use	Consumer or commercial use
Ethylbenzene	100-41-4	Arts, crafts, and hobby materials	Both
		Food packaging	Both
		Furniture and furnishings not covered elsewhere	Both
		Plastic and rubber products not covered elsewhere	Both
		Toys, playground, and sporting equipment	Consumer
Nickel	7440-02-0	Batteries	Both
		Electrical and electronic products	Both
		Other (specify)	Both
Chromium	7440-47-3	Floor coverings	Commercial
		Other (specify)	Both
Formaldehyde	50-00-0	Floor coverings	Commercial
p-Hydroxybenzoic acid (pHBA)	99-96-7	Personal care products	Both
Decamethylcyclopentasiloxane (D5)	541-02-6	Personal care products	Both
Butylated hydroxyanisole (BHA)	25013-16-5	Non-TSCA use[34]	Both

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is,*for more than half of the MTS List chemicals, manufacturers and importers do not always know if their chemicals are ending up in products being used by children.*

More broadly, some of the requested processing and use data were reported as "not known or reasonably ascertainable" by the manufacturers and importers of 78 (86%) of the 91 MTS List chemicals with any reported use information.

While the lowering of the threshold for reporting processing and use information in the next (2016) CDR cycle will provide such information for more chemicals, it will not resolve the data gaps in the available processing and use information. The amount of downstream use information "known or reasonably ascertainable by" a chemical manufacturer or importer will still be limited, regardless of the volume of production or import. This in turn limits the amount of information available to EPA on chemical uses, as well as the amount of information that EPA can make available to the public.

The only way to expand EPA's and the public's knowledge of the uses of chemicals is for EPA to collect such information directly from chemical users.

Conclusion

Our analysis has documented that there is substantial U.S. production and use of well over one hundred chemicals identified by government authorities in the U.S. and EU for their potential to cause harm to human health and the environment. Many of these chemicals are produced in very large quantities in the U.S., by many different companies at many sites and in the great majority of U.S. states. In addition, many of these chemicals are present in consumer and commercial products, indicating greater potential for exposure to these chemicals. Even more concerning, some of those chemicals are positively identified to be present in products intended for use by children.

Of additional concern is the extent of information that remains unknown or unreported to EPA and the public, whether due to volume thresholds or reporting exemptions or because EPA only requests information from chemical manufacturers and importers. While this report makes utilizes the information that EPA *has* been able to collect, our analysis is constrained by the same limitations that apply to the information EPA is able to collect and make available to the public.

How we did our analysis

As noted in the Introduction, the MTS List includes 120 entries, each for an individual chemical or a group of closely related substances. To conduct our analysis, we made three adjustments.

- First, the MTS List includes 117 individual chemicals with Chemical Abstract Services (CAS) registry numbers listed and three categories (for which the list indicates the CAS number as "various"). The basis for our analysis is a cross-comparison among lists, which requires CAS number identifiers. Therefore we identified all CAS numbers related to these categories[35] for inclusion in our analysis by searching the specific authoritative lists used to compile the MTS List.[36]

- Second, several substances that are identified by only one CAS number on the MTS List are representative of categories of closely related substances, which in some cases have additional CAS numbers listed on the authoritative lists used to compile the MTS List. We therefore included these additional CAS numbers in our analysis.[37] For example, the entry for "lead and lead compounds", represented on the MTS List by the CAS number for elemental lead, was expanded to include any specific lead compounds identified on the authoritative lists.

- Third, several entries on the MTS List represent commercial mixtures or other substances for which multiple CAS numbers may be appropriate in identifying the substances.[38] We searched the CDR data for all such CAS numbers in these cases, and combined all data matching any of these CAS numbers under the CAS number used to identify the mixture on the MTS List.[39]

All of the CAS numbers included for these group entries can be found in EDF's document "Additional information on the Hazardous 100+ list of chemicals of high concern," available upon request.

Applying these adjustments yielded a total of 216 distinct CAS numbers for the 120 entries on the MTS List.

We then compared this list of 216 CAS numbers to the following chemical lists:

- **The TSCA Inventory.** We used the most recent public version of the Inventory, dated January 2014.[40]

- **Chemicals produced or imported in the U.S.** We used the latest publicly available data from EPA on chemicals produced in or imported into the U.S. in 2011 in amounts of 25,000 pounds or more per site, and the companies that reported producing or importing them.[41] These data are periodically collected by EPA under its Chemical Data Reporting (CDR) rule.[42] The CDR data provide the following information used in our analysis:

  - the identity of reported chemicals, by name and CAS number;

  - the volume of each chemical produced or imported at each reporting site of production or import;

- the name of each company that reported production or import of each chemical, and whether they reported producing or importing the chemical, or both; and
- the location of each facility of each company that reported producing or importing each chemical.

- **Processing and use information for a subset of the chemicals reported as produced or imported in the U.S.** In addition to the manufacturing-related information provided by the EPA's CDR rule, processing and use information was required to be reported for chemical substances produced or imported at 100,000 pounds or more per site during 2011. The types of use information utilized in our analysis are:
  - consumer and commercial product categories[43]
  - whether the chemical is used in products intended for use by children[44]

In examining the required use information, we looked at additional data elements to identify the extent to which information is reported as "not known or reasonably ascertainable" by the chemical manufacturers and importers reporting under the CDR.[45]

In using our analysis and results, it is important to note that the CDR data are both site- and chemical-specific. That is, each entry in the database corresponds to a unique site-chemical combination, for a given reporting company. If that company produces more than one chemical at a site, each chemical will be listed as a separate entry. This affects our calculation of the extent of confidential business information (CBI) claims in the subset of CDR data corresponding to the MTS List chemicals. However, as it is impossible for us to know whether or not several entries for a given chemical on the CDR for which the company identity is masked as CBI are for one or multiple companies, we have to count all instances where CBI is listed for company identity as separate incidences of a CBI claim. This also paints a more accurate picture of the degree of CBI claims on the CDR, as withholding a company's identity for a company that produces dozens of chemicals is withholding more information from the public than for a company that produces one chemical at a single site and claims its identity as CBI.

Notes

[1] The authoritative lists are:
- State of California "List of Chemicals Known to Cause Cancer or Reproductive Toxicity" (Proposition 65 List),
- State of Maine "Designated Priority Chemicals" and "List of Chemicals of High Concern",
- State of Minnesota "List of Priority Chemicals",
- State of Washington "List of Chemicals of High Concern to Children,"
- United States Environmental Protection Agency "Existing Chemicals Action Plans," and
- European Union: "Authorisation List" and "Candidate List of Substances of Very High Concern for Authorisation."

[2] As of the date of this report, there are 104 chemicals or chemical categories on the first sublist and 16 chemicals or chemical categories on the second, for a combined total of 120 chemicals and chemical categories. For additional information on the types of chemicals included in the "Hazardous Hundred+" as additional chemicals of high concern, see http://mindthestore.saferchemicals.org/methodology.

[3] For more information on the Chemical Data Reporting (CDR) rule, see EPA's website: (http://www.epa.gov/cdr/index.html), EPA's fact sheets providing basic information for the 2012 CDR (http://www.epa.gov/cdr/pubs/guidance/1st_cdr_basic_factsheet.pdf) and a snapshot of the data collected in 2012 (http://www.epa.gov/cdr/pubs/guidance/2nd_cdr_snapshot.pdf).

[4] To view the complete set of public data collected under the 2012 CDR, visit the U.S. EPA's Chemical Data Access Tool (CDAT): http://java.epa.gov/oppt_chemical_search/ and download the public version of the CDR database in Microsoft Access, linked to in the right "Highlights" sidebar.

[5] Under the 2012 CDR, EPA collected data on a total of 7,674 chemicals, submitted by 1,528 reporting companies for activities occurring at 4,573 sites of manufacturing or import. See EPA's fact sheet providing basic information on the CDR for more information: http://www.epa.gov/cdr/pubs/guidance/1st_cdr_basic_factsheet.pdf. EPA issued this fact sheet with the following disclaimer: "The CDR data described in this factsheet is a sub-set of the complete CDR data because confidential business information is not included. The figures presented herein may be an underestimate."

[6] For more information, see "24. Reporting Standard" in http://www.epa.gov/cdr/pubs/guidance/faqs-chap23-24-25.html.

[7] See http://www.epa.gov/oppt/existingchemicals/pubs/transparency.html for information on EPA's efforts to increase transparency of chemical information provided to the public.

[8] See http://www.epa.gov/cdr/pubs/guidance/faqs-chap31.html for information on upfront substantiation of confidentiality claims under the CDR.

[9] Where EPA does not disclose specific chemical identities or CAS numbers for substances on the confidential inventory, a unique accession number is provided instead. The fraction of chemical identities claimed CBI is calculated as the number of unique accession numbers out of the total number of chemicals reported to the CDR. See section 26.2 of "FAQ: 2012 Chemical Data Reporting, Completing Form U" at http://www.epa.gov/cdr/pubs/guidance/faqs-chap26.html for an explanation of EPA's use of accession numbers, and see the CDR database, available under the "Access the Data" section of EPA's CDR page, http://java.epa.gov/oppt_chemical_search/, for a list of accession numbers.

[10] Appendices 1-5 are provided in a separate file accompanying this report at: http://www.edf.org/health/ToxicsAcrossAmericaAppendices.pdf.

[11] The identities of about 17,000 chemicals on the TSCA Inventory are confidential and hence are not included in the public version. U.S. Environmental Protection Agency, "EPA's Initiatives on Safe Chemicals." Steve Owens, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, presentation dated November 17, 2011, available at: http://www.epa.gov/region1/greenchemistry/pdfs/SteveOwens.pdf.

[12] For more information on modifications the CDR made to the Inventory Update Reporting (IUR) Rule, see http://www.epa.gov/cdr/pubs/IUR-fact-sheet7-18-11.pdf.

[13] Exempted chemical groups include polymers, naturally occurring chemical substances, certain forms of natural gas and water. However, certain polymers or forms of natural gas are not exempt if they have been subject to certain TSCA actions, such as Enforceable Consent Agreements. In addition, exemptions from reporting apply to chemicals that are: a) produced in small quantities for research and development; b) imported as part of an article; c) manufactured as an impurity, byproduct (under certain circumstances), or non-isolated intermediate; or d) manufactured by persons who qualify as small manufacturers. Several additional categories of chemicals are granted partial reporting exemptions. See http://www.epa.gov/cdr/pubs/guidance/faqs-chap11-12.html and http://www.gpo.gov/fdsys/pkg/CFR-2012-title40-vol32/pdf/CFR-2012-title40-vol32-sec711-6.pdf.

[14] Where EPA does not disclose specific chemical identities or CAS numbers for substances on the private inventory, a unique accession number is provided instead. The number of chemical identities claimed CBI on the 2012 CDR is the number of unique accession numbers: 451 (6% of total chemicals on the CDR).

[15] See U.S. EPA, "Chemical Data Reporting, Fact Sheet: Basic Information" for a comparison of submissions between 2006 IUR and 2012 CDR and the number of chemicals reported for each at http://www.epa.gov/cdr/pubs/guidance/1st_cdr_basic_factsheet.pdf. See Environmental Defense Fund's "Across the Pond" report,

Appendix 1 (http://www.edf.org/health/reports/across-the-pond), for an analysis of fluctuations in chemicals reported in the earlier 2006 and 2002 reporting cycles. Analysis of fluctuations between 2012 and 2006 reporting cycles: unpublished Environmental Defense Fund data.

[16] Individual production volumes are available in the Microsoft Access Database of CDR data provided by EPA. To find aggregate production volumes for a chemical, use the U.S. EPA's Chemical Data Access Tool (CDAT) available at: http://java.epa.gov/oppt_chemical_search/. A search for a specific chemical in the CDR tab yields results that include the National Production Volume.

[17] In our analysis, we combined the data for several CAS numbers under one CAS number if the substance represented a mixture (see "How we did our analysis" for details). For the following chemicals, the CAS numbers qualify for the HPV category because production volume data were aggregated for all CAS numbers represented by the mixture:

Toluene diisocyanate:
- Toluene diisocyanate (CAS 26471-62-5): 250,000,000–500,000,000 lb./year
- 2,6'-TDI (CAS 91-08-7): withheld for CBI (not counted under CBI category)
- 2,4'-TDI (CAS 584-84-9): 50,000,000–100,000,000 lb./year

Methylene diisocyanate:
- Methylene diisocyanate (CAS 26447-40-5): 168,430,128 lb./year
- 4,4'-MDI (CAS 101-68-8): 416,217,187 lb./year
- 2,2'-MDI (CAS 5873-54-1): withheld (2 CBI claims for production volume)

Short-chain chlorinated paraffins:
- Paraffin waxes and hydrocarbon waxes, chloro (CAS 63449-39-8): 10,000,000 to 50,000,000 lb./year
- Paraffins, chloro (CAS 61788-76-9): 25,918,167 lb./year

[18] This breakdown of companies adds up to more than the total number of companies because some companies manufacture, import and/or make CBI claims regarding the same chemicals.

[19] Appendices 1-5 are provided in a separate file accompanying this report at: http://www.edf.org/health/ToxicsAcrossAmericaAppendices.pdf.

[20] The two chemicals not publicly reported are: Dichromium tris(chromate) (CAS 24613-89-6) and 2-Ethylhexyl-2,3,4,5-tetrabromobenzoate (CAS 183658-27-7).

[21] The counts of sites per CAS number include entries for which site identity and location are claimed CBI. In the Microsoft Access CDR Database query, each entry represents a distinct CAS number and site combination for a reporting company. Therefore, a query for a CAS number with a CBI site still indicates a unique CAS number – site combination for the reporting company and can be counted as a distinct site.

[22] Appendices 1-5 are provided in a separate file accompanying this report at: http://www.edf.org/health/ToxicsAcrossAmericaAppendices.pdf.

[23] Appendices 1-5 are provided in a separate file accompanying this report at: http://www.edf.org/health/ToxicsAcrossAmericaAppendices.pdf.

[24] For more information, see section 24.1 of EPA's FAQs on the CDR, available here: http://www.epa.gov/cdr/pubs/guidance/faqs-chap23-24-25.html.

[25] For more information, see page 2 of EPA's "Fact sheet on Top Uses of Chemicals: A Snapshot of the Data": http://www.epa.gov/cdr/pubs/guidance/2nd_cdr_snapshot.pdf.

[26] For more information, see page 2 of EPA's "Fact sheet on Top Uses of Chemicals: A Snapshot of the Data": http://www.epa.gov/cdr/pubs/guidance/2nd_cdr_snapshot.pdf.

[27] Manufacturers and importers of a given chemical over the reporting threshold may have only reported industrial uses for the chemicals. Such companies are not included in our analysis because we only looked at companies reporting consumer or commercial uses.

[28] For additional information on the next CDR reporting cycle, see: http://epa.gov/cdr/tools/index.html#2016.

[29] Numbers do not necessarily add to total because the same chemical may be reported for both a commercial and consumer use.

[30] For EPA's analysis of chemical uses across all chemicals reported under the CDR, see: http://www.epa.gov/cdr/pubs/guidance/cdr_factsheets.html.

[31] This figure does not include any uses reported as CBI, NKRA or "other (specify)," as we cannot identify specific uses in these cases. Although "other (specify)" is reported in the CDR data for applicable use, the specification of use category provided by companies is currently not available online. Therefore we did not consider it to be an identified use of chemical. See "How we did our analysis" for details.

[32] This figure does not include any uses reported as CBI, NKRA or "other (specify)," as we cannot identify specific uses in these cases.

[33] For additional information, see section 28.19 of EPA's FAQs on the CDR, "How is "intended for use by children" defined for purposes of CDR?", available here: http://www.epa.gov/cdr/pubs/guidance/faqs-chap28.html.

[34] Some companies reporting use information are manufacturing or importing chemicals for both TSCA and non-TSCA uses (e.g., a use regulated by FDA). In these cases, the downstream use may be reported as a "non-TSCA use". For additional information, see section 11 of EPA's FAQs for the CDR: http://www.epa.gov/cdr/pubs/guidance/faqs-chap11-12.html.

[35] The chemical categories not identified on the MTS List by CAS numbers are: benzidine-based and benzidine congener-based dyes (Azo dyes), polybrominated diphenyl ethers (PBDEs); and other organotins.

[36] The authoritative lists are:
- State of California "List of Chemicals Known to Cause Cancer or Reproductive Toxicity" (Proposition 65 List),
- State of Maine "Designated Priority Chemicals" and "List of Chemicals of High Concern",
- State of Minnesota "List of Priority Chemicals",
- State of Washington "List of Chemicals of High Concern to Children,"
- United States Environmental Protection Agency "Existing Chemicals Action Plans," and
- European Union: "Authorisation List" and "Candidate List of Substances of Very High Concern for Authorisation."

[37] The entries on the MTS List that were expanded to include additional CAS numbers include: Hexabromocyclododecane (HBCD), antimony trioxide, arsenic & arsenic compounds, beryllium & beryllium compounds, cadmium & cadmium compounds, chromium & chromium compounds, cobalt & cobalt compounds, lead & lead compounds, mercury & mercury compounds, nickel & nickel compounds, Diisodecyl phthalate (DIDP), Diisononyl phthalate (DINP), toluene diisocyanate (TDI), nonylphenol ethoxylates (NPEs), nonylphenol (NP) and methylene diisocyanate (MDI).

[38] These entries include: toluene diisocyanate (TDI), methylenediphenyl diisocyanate (MDI) and short-chain chlorinated paraffins (SCCPs).

[39] Short-chain chlorinated paraffins are identified in the CDR under a CAS number that is not the same as that used on the MTS List. The CAS number for this category on

the MTS List (85535-84-8), which originates from the EU "Candidate List", does not appear on the U.S. TSCA Inventory or the CDR. Instead, we conducted searches for this substance using several CAS numbers identified as including SCCPs in EPA's action plan: 63449-39-8, 71011-12-6, 68920-70-7, and 61788-76-9. Data for these CAS numbers has been consolidated under Paraffin waxes and hydrocarbon waxes, chloro (CAS # 63449-39-8). The EPA Action Plan refers to CAS numbers that in some but not all cases include short chain chlorinated paraffins. Because these CAS numbers are broader than just the short chain category, they may include records that do not actually correspond to SCCPs. See EPA's Action Plan on SCCPs for additional information: http://www.epa.gov/oppt/existingchemicals/pubs/sccps_ap_2009_1230_final.pdf.

[40] The non-confidential portion of the U.S. TSCA Inventory is available at http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/howto.html. The data we used in this report were current through January 2014.

[41] The non-confidential portion of the CDR data is available for download in Microsoft Access format at http://java.epa.gov/oppt_chemical_search/ (see "Highlights"). Additionally, the CDR results can be searched using the Chemical Data Access Tool. The 2012 CDR data were originally released on February 11, 2013 and were updated on April 4, 2013. The data we used in this report were current as of January 16, 2014.

[42] For more information on EPA's CDR, see http://www.epa.gov/cdr/pubs/guidance/basic.html.

[43] For the listing of available product category codes, see Table 4-12 of the document http://www.epa.gov/cdr/tools/InstructionsManual.013112.pdf.

[44] According to the EPA, "for purposes of the CDR, "intended for use by children" means the chemical or mixture is "used in or on a product that is specifically intended for use by children age 14 or younger." See http://www.epa.gov/cdr/pubs/guidance/2nd_cdr_snapshot.pdf.

[45] The additional data elements for processing and use information include:
- Percent production volume by use
- Maximum concentration by use
- Number of commercial workers by use

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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 JENNIFER MCPARTLAND

I, Jennifer McPartland, declare as follows:

1. My name is Jennifer McPartland. I am over 18 years of age. The information in this declaration is based on my personal knowledge, experience, and knowledge of the pertinent literature. By virtue of my education, training, occupation, and knowledge of the pertinent scientific

literature, I consider myself an expert on scientific and policy issues, and market-based strategies related to chemical hazards and risks.

2. I am a senior scientist within the Health Program at Environmental Defense Fund (EDF). I have held this position for 7.5 years. I pursued post-doctoral research and received my doctorate degree in microbiology (2008) from the University of Chicago. The research I conducted over this period of time spanned the fields of microbiology and molecular biology. I received a bachelor of science in chemistry with a specialization of biochemistry from the University of Virginia (2003).
3. I currently serve as a member of the U.S. Environmental Protection Agency's (EPA's) Board of Scientific Counselors (BOSC) Chemical Safety for Sustainability (CSS) Subcommittee. Advancing new predictive approaches to understanding chemical hazards and risks is a priority area of research within EPA's CSS research program. As a member of the BOSC CSS Subcommittee, I provide scientific advice and recommendations to EPA on its research efforts to advance understanding of chemical hazards and risks—both to people and the environment—to improve their safe production, use, and disposal.
4. I have attached a list of my recent publications as Attachment A.

5. 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.
6. One of the Health Program's goals is to significantly reduce exposure to toxic chemicals in consumer products, air, water, and food. The Health Program works to transform data into meaningful, actionable information that enables smarter, health-protective policies and practices across multiple sectors including government and industry.
7. Another goal of the Health Program is to keep our members and the public informed about chemical risks and exposures. EDF has long studied the public's exposure to chemical substances, and the public health and environmental effects of chemical substances. EDF goes to great lengths to inform the public about these issues.
8. One of my major activities at EDF is to inform our members and the public generally about the health and environmental hazards, exposures, and risks of chemical substances.
9. In my experience and opinion, information about both chemical hazards and exposures is required to understand and effectively communicate the potential risks chemicals pose to human health and the environment. EDF cannot effectively collaborate with researchers or other relevant experts

to characterize the potential hazards, exposures, and risks a chemical poses without knowledge of specific chemical identity. As a consequence, lack of public access to specific chemical identities harms EDF's efforts to comprehensively and effectively 1) communicate chemical concerns with the broader public, and 2) shape policy and market-based initiatives to reduce harmful chemical exposures.

10. In my expert opinion, it is extremely difficult, if not impossible, to obtain or generate meaningful information about potential chemical hazards, exposures, and risks without knowledge of the specific identity of a chemical—that is, a chemical's unique chemical structure. As discussed further below, specific chemical identity is required to effectively and reliably conduct many chemical analyses aimed at predicting potential hazards, exposures, and risks of a specific chemical substance. Additionally, knowing the specific identity of a chemical is required to effectively and meaningfully identify and use hazard, exposure, and risk information associated with that chemical. Because the vast majority of chemicals in commerce lack sufficient

experimentally measured hazard or exposure information,[1,2] chemical evaluations often rely heavily on chemical structure-based approaches to predict chemical hazards and exposures. Effective and reliable application of such approaches requires knowledge of specific chemical identity.

11. In my expert opinion, specific chemical identity is required to effectively and reliably apply structure-based predictive approaches to characterize a chemical's hazards and exposures. The scientific, regulatory, industry, and public interest communities often use structure-based approaches to predict or estimate potential chemical hazards and exposures. Indeed, a cutting-edge chemical research institution at EPA, the National Center for Computational Toxicology, notes "[t]he foundation of chemical safety testing relies on chemistry information such as high-quality chemical structures and physical chemical properties. This information is

[1] Judson, Richard, et al. "The Toxicity Data Landscape for Environmental Chemicals." *Environmental Health Perspectives*, vol. 117, no. 5, 22 Dec. 2008, pp. 685–695., doi:10.1289/ehp.0800168.

[2] Egeghy, Peter P., et al. "The exposure data landscape for manufactured chemicals." *Science of The Total Environment*, vol. 414, 1 Jan. 2012, pp. 159–166., doi:10.1016/j.scitotenv.2011.10.046.

used by scientists to predict the potential health risks of chemicals."[3] For example, under TSCA, EPA relies on an assortment of prediction models and tools within its Sustainable Futures program to review new chemicals for potential risk.[4] The majority of the Sustainable Future approaches are chemical structure-based, that is, they seek to predict risk-relevant properties of a new chemical based on its structural features; this includes the extent to which it is structurally similar to other chemicals for which risk-relevant information exists. These approaches are designed to predict risk-related chemical properties ranging from toxicity to aquatic organisms (Ecological Structure-Activity Relationships Program (ECOSAR)) and cancer potential (OncoLogic) to physical chemical properties and fate in the environment (Estimation Programs Interface (EPISuite)).[5,6] Relatedly, the Organization for Economic Co-operation

[3] "Chemistry Dashboard." *EPA*, Environmental Protection Agency, 30 Mar. 2017, www.epa.gov/chemical-research/chemistry-dashboard.
[4] "About Sustainable Futures." EPA, Environmental Protection Agency, 6 Mar. 2017, www.epa.gov/sustainable-futures/about-sustainable-futures#what.

[5] "Models and tools developed by EPA to assess hazard under TSCA." EPA, Environmental Protection Agency, 9 Mar. 2017, https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-hazard-under-tsca#models.

[6] "EPA's fate and exposure models and tools." EPA, Environmental Protection Agency, 13 Apr. 2017, https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate.

and Development (OECD) QSAR ToolBox uses chemical structure information to estimate chemical hazards and environmental fate properties such as the propensity to persist or bioaccumulate in living organisms. Knowledge of specific chemical identity is required to effectively and reliably use these tools to discern potential risk concerns of a chemical.

12. For chemicals for which we don't know the specific identity, lack of access to experimentally measured information on risk-relevant chemical properties, and an inability to reliably predict such properties, reduces EDF's ability to fulfill a primary goal to "significantly reduce exposure to high-risk chemicals in consumer products, water, and food."[7]

13. In my experience at EDF, I worked on a project intended to spur innovation to develop safer preservatives for use in personal care products. The project led to the development of a framework for driving safer chemicals and products into the marketplace. The primary output of the framework is a uniformly-developed set of toxicological information that can be used to directly compare different chemicals in a functional class (e.g., preservatives). EDF contracted ToxServices, a scientific consulting firm, to develop hazard and environmental fate assessments

[7] Pathways 2025 EDF Strategic Plan. Environmental Defense Fund. 2017.

for various chemical preservatives used in personal care products. ToxServices used a number of models to support the development of the assessments; models included OncoLogic, EPI Suite, ECOSAR, OECD QSAR Toolbox, Toxtree, and VEGA. These models generally rely on knowledge of specific chemical identity. Information provided by the models was integral to developing the comparative preservative chemical assessments, which in turn were central to EDF public-facing materials, which included a project report, website, and webinar.[8] I have attached a copy of the project report as Attachment B. Thus, knowledge of specific chemical identities has assisted me in my advocacy work at EDF.

14. In my expert opinion, generic chemical names cannot be substituted for specific chemical identities in the course of obtaining or generating information on potential chemical hazards, exposures, and risks. Generic names by their very nature refer to multiple chemicals, significantly hampering one's ability to understand and characterize the potential hazards, exposures, and risks associated with any particular chemical. Additionally, even small structural differences among chemicals can have a significant impact on their potential hazards, exposures, and risks.

[8] "Smart Innovation: The Opportunity for Safer Preservatives." *Environmental Defense Fund*, http://business.edf.org/smart-innovation-the-opportunity-for-safer-preservatives/.

EDF discussed these issues extensively in comments we submitted to the Office of Information and Regulatory Affairs, within the U.S. Office of Management and Budget on a U.S. EPA 2010 policy and 2011 regulatory proposal relating to confidentiality claims for chemical identity in data from health and safety studies submitted to EPA under TSCA. See Attachment C.

15. In my expert opinion, specific chemical identity is also generally required for conducting environmental monitoring or human biomonitoring of chemical substances. It is not possible to identify and measure the presence of a specific chemical substance in environmental or biological media without knowledge of its specific identity. The contamination of the Cape Fear River basin in North Carolina by perfluoro-2-propoxypropanoic acid (GenX) provides a timely example of this. A seminal study conducted by a team of researchers led by Dr. Detlef Knappe at North Carolina State University first identified contamination of drinking water by GenX, a replacement for the well-established toxic chemical perflurooctanoic acid (PFOA). Knowing the specific structural identity of GenX, now an emerging chemical of concern, allowed Dr. Knappe's team to identify and analyze for this substance (and related substances) in raw and treated water samples from

a drinking water treatment plant located downstream of a fluorochemical manufacturer in the Cape Fear River Basin.[9] Dr. Knappe's discovery, permitted only through knowledge of specific chemical identities, has helped to spur nationwide attention to contamination of various environmental media by perfluorinated chemicals. This in turn has led to a number of community, legal, and regulatory actions. EDF has relied on information about GenX in Cape Fear River Basin in our advocacy efforts.[10,11]

16. In my expert opinion, the ability to detect and measure specific chemicals through biomonitoring—that is, detecting and measuring the presence of environmental chemicals in collected biological samples, including urine, blood, and tissue—requires knowledge of specific chemical identity. The U.S. Centers for Disease Control and Prevention

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[9] Sun, Mei, et al. "Legacy and Emerging Perfluoroalkyl Substances Are Important Drinking Water Contaminants in the Cape Fear River Watershed of North Carolina." *Environmental Science & Technology Letters*, vol. 3, no. 12, 2016, pp. 415–419., doi:10.1021/acs.estlett.6b00398.

[10] "Over 100 Residents of Communities Impacted by PFCs Demand Protection of EPA Science Program." *Environmental Defense Fund*, www.edf.org/media/over-100-residents-communities-impacted-pfcs-demand-protection-epa-science-program.

[11] "All Eyes on NC Senate as State House Acts on Chemical Pollutants." *Environmental Defense Fund*, www.edf.org/media/all-eyes-nc-senate-state-house-acts-chemical-pollutants.

(CDC) Division of Laboratory Sciences manages the National Biomonitoring Program (NBP), which provides a periodic assessment of exposure of the U.S. population to over 300 environmental chemicals and toxic substances.[12] Results of the National Biomonitoring Program are publicly reported in the National Report on Human Exposure to Environmental Chemicals (National Exposure Report), providing the most comprehensive knowledge base of environmental chemical exposures occurring across the American population.

17. In my experience, EDF relies on CDC's reports, as well as other exposure biomonitoring information, to understand and communicate with the public and with businesses about potential health risks of chemical exposures in our efforts to drive health protective regulatory and marketplace action. For example, EDF has written blogs and developed infographics on human exposure to chemicals that relied, in

[12] "National Biomonitoring Program." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 7 Apr. 2017, www.cdc.gov/biomonitoring/.

part, on CDC biomonitoring information.[13,14,15] Moreover, EDF's ability to recommend chemicals for the CDC to include in the National Biomonitoring Program requires knowledge of specific chemical identity.

18. In sum, in my experience, the ability to identify specific chemicals through environmental and human biomonitoring is contingent on knowledge of specific chemical identity. Real-world monitoring for chemicals in the environment or in people is central to EDF's ability to understand, communicate, and act on potential environmental and health risks resulting from chemical exposures.

[13] McCormick, Lindsay. "Wearable wristbands detect flame retardants." *EDF Health*, 2 June 2016, http://blogs.edf.org/health/2016/06/01/wearable-wristbands-detect-flame-retardants/.

[14] Denison, Richard. "Hitting 'em where it hurts: BPA reduces sperm quantity and quality in male workers." *EDF Health*, 25 Mar. 2014, http://blogs.edf.org/health/2010/10/28/hitting-em-where-it-hurts-bpa-reduces-sperm-quantity-and-quality-in-male-workers/.

[15] Denison, Richard. "EDF Special Report: Don't assume the chemicals in your household are safe." *Environmental Defense Fund*, Spring 2015, www.edf.org/sites/default/files/specialreport_spring2015.pdf (p. 5).

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

Dated: 3/2/18

JENNIFER MCPARTLAND

McPartland
Attachment A

Attachment A

Jennifer McPartland Recent Relevant Publications

Lam, J, et al. (2017) Developmental PBDE Exposure and IQ/ADHD in Childhood: A Systematic Review and Meta-Analysis. Environ Health Perspect. 125(8).

McPartland J, Dantzker HC, Portier CJ. (2017). Elucidating Environmental Dimensions of Neurological Disorders and Disease: Understanding New Tools from Federal Chemical Testing Programs. Sci Total Environ. 593-594:634-640.

Malloy, T, et al. (2017) Advancing alternatives analysis: The role of predictive toxicology in selecting safer chemical products and processes. Integr Environ Assess and Manage. 13(5)915-925.

Bennet, D et al. (2017) Project TENDR: Targeting Environmental Neuro-Developmental Risks The TENDR Consensus Statement. Environ Health Perspect. 124(7):A118-22.

Stephens, ML et al. (2016). The Emergence of Systematic Review in Toxicology. Toxicol Sci. 152(1):10-16.

McPartland J, Dantzker HC, Portier CJ. (2015). Building a robust 21st century chemical testing program at the U.S. Environmental Protection Agency: recommendations for strengthening scientific engagement. Environ Health Perspect. 123(1):1–5.

Accompanying Science Selection Piece

Arnold C. (2015). ToxCast™ wants you: recommendations for engaging the broader scientific community. Environ Health Perspect. 123(1):A20.

McPartland, J., Lam, J., Lanier-Christensen, C. (2014). A Valuable Contribution toward Adopting Systematic Review in Environmental Health. Environ Health Perspect. 122(2):A2.

EDF Toxicity Testing in the 21st Century Online Primer (2013): http://bit.ly/1f4FXnK

EDF Health Blog Series (2010-current): http://bit.ly/2fLhGNm

McPartland
Attachment B

March 1, 2012

Cass R. Sunstein
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
1650 Pennsylvania Avenue, N.W.
Washington, DC 20503

By Email & Hand Delivery

Re: CBI: PMN Amendments Claiming Chemical and Microorganism Identity as Confidential in Data From Health and Safety Studies Submitted Under TSCA Prior to the Commencement of Manufacture

Dear Administrator Sunstein:

The BlueGreen Alliance, Breast Cancer Fund, Clean Water Action/Clean Water Fund, Environmental Defense Fund, Earthjustice, National Medical Association, Science & Environmental Health Network, and Women's Voices for the Earth write to express support for the U.S. Environmental Protection Agency's (EPA's) 2010 policy and 2011 regulatory proposal for the review of confidentiality claims related to chemical or microorganism identity in data from health and safety studies submitted to the EPA under the Toxic Substances Control Act (TSCA). *See Regulatory Review Dashboard,* RIN 2070-AJ87, Office of Information and Regulatory Affairs, http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201110&RIN=2070-AJ87 (last visited Feb. 28, 2012).[1] EPA's actions are intended to align review of confidential business information (CBI) claims with the statutory language of TSCA and bring long overdue daylight to health and safety studies, as intended by the statute.

Despite TSCA's explicit language making clear that data from health and safety studies are not protected from disclosure by claims of confidentiality, EPA historically accepted such claims without review even as to health and safety data, thereby preventing disclosure of health and safety information, including chemical identity. In January 2010, EPA announced a new general practice of reviewing submissions under TSCA Section 8(e) (substantial risk notices) for claims that the identity of a chemical listed on the public portion of the Chemical Substances

[1] Since the proposed rule has not yet been published for notice and comment, our information about this proposed rule is gleaned from the online description at www.reginfo.gov.

Inventory of TSCA (the Inventory) is CBI. *See* Claims of Confidentiality of Certain Chemical Identities Submitted under Section 8(e) of the Toxic Substances Control Act, 75 Fed. Reg. 3462 (Jan. 21, 2010). In accordance with the January announcement, where a health and safety study submitted under Section 8(e) involves a chemical identity listed on the public portion of the Inventory, EPA now reviews such claims and "expects to find that the chemical identity clearly is not entitled to confidential treatment." *Id*. In May, 2010, EPA announced that it would initiate a general practice of reviewing confidentiality claims for chemical identities in all health and safety studies, and in data from health and safety studies submitted under TSCA even if they are not listed on the public Inventory. *See* Notice of General Practice of Reviewing Confidentiality Claims for Chemical Identities in Health and Safety Studies and Data from Health and Safety Studies Submitted Under the Toxic Substances Control Act, 75 Fed. Reg. 29,754 (May 27, 2010) (the May Notice). The current proposal to amend regulations related to disclosure of health and safety information submitted to EPA during the premanufacture notice (PMN) process would build upon EPA's prior efforts to evaluate CBI claims in the context of health and safety studies in a manner that is consistent with the language and intent of TSCA Section 14.

In a recent White Paper made public on January 19, 2012, the American Chemistry Council (ACC) makes sweeping assertions about the potential impact of EPA's policy, not only arguing against EPA's proposed regulations related to health and safety studies submitted during the PMN process, but launching a broadside attack on the policies announced by EPA in 2010. *See generally* ACC White Paper, TSCA Protects Confidential Chemical Identities in Health and Safety Studies from Disclosure (January 19, 2012) (ACC White Paper). As discussed below, ACC's argument has a number of searing flaws:

- Perhaps most significantly, ACC ignores the plain language of TSCA and substitutes a balancing test weighing interests against one another. Section 14 of TSCA, however, contains a general provision governing disclosure of data outside of the context of health and safety studies, 15 U.S.C. § 2613(a), which protects information that is exempt from disclosure under the Freedom of Information Act as a trade secret, and another explicit provision applicable to "Data from health and safety studies," 15 U.S.C. § 2613(b), which makes clear that any data reported to EPA from a health and safety study is not protected from disclosure unless it qualifies as CBI and reveals process or, in the case of a mixture, portion information. Information about chemical identity in health and safety studies, thus, is not protected unless it is CBI and would reveal process or portion information, a determination that should be made through the substantiation process as EPA reviews CBI claims.
- ACC mischaracterizes the legislative history of TSCA. The legislative record makes clear that Congress heard testimony about the protection of CBI and intended to allow the disclosure of chemical identity within health and safety studies. *See, e.g.*, H.R. Rep. No. 94-1341, at 51 (1976), Legis. Hist. at 458 ("the Committee intends to protect confidential trade secret information respecting the specific *formulation* of a mixture.

However, the Committee does not intend to prohibit the Administrator from disclosing the *chemical substances* comprising the mixture….") (emphasis added).

- ACC's proposal to substitute generic names for chemical identities – where those identities would not reveal process or portion information and, thus, would not fit under the exceptions allowed by Section 14(b) – is not consistent with the statutory mandate. As described below, the use of generic identifiers as a substitute for the disclosure of chemical identity is contemplated only for information published in the Federal Register in compliance with Section 5 but, even then, not in the context of health and safety studies. Moreover, the use of generic names is inadequate to make available health and safety information to the public.
- ACC states that disclosure of chemical identity data in health and safety studies "may have serious adverse impacts on innovation and on small business" and "may help drive chemical industry jobs overseas," but offers no quantification or meaningful analysis of such claims. ACC provides no evaluation of the direct or indirect costs and benefits and no evidence that in fact the economic and social costs of EPA's policy outweigh its benefits. Indeed, ACC completely ignores the benefits of transparency to innovation and stimulation of the economy. ACC's arguments are simply an attempt to cast aspersions on policy that furthers this Administration's commitments to greater transparency and open scientific inquiry.[2]

Below please find a more detailed discussion of EPA's proposal, the requirements of TSCA Section 14, Congressional intent to make information about chemical identity in the context of health and safety studies public, and other policy considerations. At the outset, though, we want to outline our agreement with some aspects of the ACC White Paper.

- First, where disclosure of confidential chemical identity would also reveal process or portion information, that chemical identity falls under the explicit exceptions in Section 14(b) and would be protected from disclosure.[3]

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[2] In a one page handout released on January 20, 2012 for a meeting with OMB, industry representatives offered one anecdotal example of the possible adverse impact on innovation, focusing on what disclosure might have meant for Proctor & Gamble, which delivered a PMN that included a significant number of health and safety studies to EPA. *TSCA: PMN Amendments Claiming Chemical Identity in Studies as CBI,* ACC/ACI/IFRA/OMB Meeting Talking Points (January 20, 2012), http://www.whitehouse.gov/sites/default/files/omb/assets/oira_2070/2070_01202012-2.pdf. The vast majority of PMNs, however, include no health and safety studies. E-mail from Greg Schweer, Chief, New Chemicals Management Branch, EPA, to Richard Denison, Senior Scientist, Environmental Defense Fund (Feb. 29, 2012) (on file with author) (more than 80% of PMNs include no health and safety study).

[3] *See* ACC White Paper at 2; however, the ACC White Paper conflates the exception with the rule. EPA's policies call for substantiation of CBI claims. EPA has not until now required substantiation of CBI claims for chemical identity made with the submission of PMNs. In order to maintain chemical identity as confidential, however, the submitter must reassert and substantiate claims with the Notice of Commencement to Manufacture (NoC). If disclosure of a chemical identity that otherwise qualifies as CBI would, in fact, reveal process or portion information, then the CBI claim would be substantiated. ACC inexplicably argues, though, that the fact that "some" chemical identities can reveal process

- Second, Section 14(b) does not cover R & D chemicals or mixtures, and thus excludes health and safety studies of R & D chemicals and R & D mixtures.[4]
- Third, EPA can and should require up-front substantiation of CBI claims.[5]
- Fourth, EPA can and should require reassertion and re-substantiation of CBI claims, allowing claims that are not reasserted and re-substantiated to expire.[6]

As discussed below, we urge OIRA to approve the publication of EPA's proposed PMN Amendments regarding claims of confidentiality related to data in health and safety studies submitted under TSCA. The proposal is an important step toward making health and safety information available to the public and will help to bring agency action in line with the mandates and purpose of TSCA.

I. EPA's Proposed Regulation is a Long Overdue Step Toward Bringing Practice into Line with the Intent and Mandate of TSCA and with This Administration's Commitment to Transparency and Scientific Inquiry

Health and safety studies are submitted to EPA under various sections of TSCA, including Section 4 (testing requirements), Section 5 (pre-manufacture notices), Section 8(a)(2)(E) (report of existing data on environmental and health effects), Section 8(d) (submission of health and safety studies by manufacturers, processors, and distributors of chemical substances or mixtures in commerce or those who propose to manufacture, process or distribute chemical substances or mixtures) and Section 8(e) (substantial risk notices). *See* 15 U.S.C. §§ 2603, 2604, 2607(a), (d)-(e). For too long, health and safety information, even including information indicating that chemical substances or mixtures present a substantial risk of injury to health or the environment, has been shielded from the public by EPA's passive acceptance of CBI claims. For too long key health and safety information about chemicals that are planned for use in the marketplace has been kept secret. EPA's 2010 policies and the current proposal regarding health and safety information submitted to EPA as part of the PMN process are welcome steps toward making more health and safety information available to the public in accordance with TSCA Section 14(b).

Historically, critical health and safety information has been shielded from public view because of both submitters' assertions of excessive and often unfounded CBI claims and the failure of EPA to routinely review and reach determinations as to the legitimacy of those claims.

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information somehow supports its argument that, more broadly, TSCA protects chemical identity. *See* ACC White Paper at 13.

[4] *See* ACC White Paper at 2. Section 14(b) applies to any health and safety study with respect to any chemical substance or mixture that "has been offered for commercial distribution," for which testing is required under Section 4, or for which a PMN or Significant New Use Notice (SNUN) is required under Section 5. 15 U.S.C § 2613(b)(1)(A). By its terms, Section 14(b) does not apply to R & D chemicals and mixtures, and is triggered at the point of the premanufacture notice. *See id., see also* 15 U.S.C. § 2604.

[5] *See* ACC White Paper at 6.

[6] *Id.*

See Sheila A. Ferguson, et al., EPA-HQ-OPPT-2002-0054-0074, Influence of CBI Requirements on TSCA Implementation, Hampshire Research Assocs. (Mar. 1992), at iii ("While there are several circumstances under which data submitted by companies are and should be handled as legitimate trade secrets, the majority of the confidentiality claims affecting data submitted under TSCA have not been substantiated, and a significant fraction of these claims would appear not to be supportable under the statute."). Nineteen years ago, EPA identified "inappropriate confidentiality claims" as impairing "the dual goals of public education about chemical substances and public participation" that were enshrined in TSCA. *See* EPA Office of Pollution Prevention and Toxics, Final Action Plan: TSCA Confidential Business Information Reform 5 (Jun. 20, 1994) (Final Action Plan). EPA's Final Action Plan stated, "The unmistakable purpose behind the participatory opportunities provided in TSCA is to afford the public the chance to contribute meaningfully to the regulatory process" and indicated that inappropriate CBI claims were thwarting the legislative purpose of TSCA. *Id.* at 3, 5. Nonetheless, industry claims of CBI protection for health and safety information and, in particular, for chemical identity, have continued unabated and virtually unchecked.

A study undertaken by the U.S. Governmental Accountability Office (GAO) in 2005 acknowledged the problem, recognizing that under TSCA "chemical companies claim much of the data submitted as confidential." GAO, GAO-05-458, Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program, at introduction (2005). The GAO noted the relevance of information provided under TSCA to the general public:

> Individual citizens or community groups may have a specific interest in information on the risks of chemicals that are produced or used in nearby facilities. For example, neighborhood organizations can use such information to engage in dialogues with chemical companies about reducing chemical risks, preventing accidents, and limiting chemical exposures.

Id. at 32. At the time of its study, the GAO reported that although "EPA has the authority to evaluate the appropriateness of these confidentiality claims," the agency stated that it lacked the resources to challenge large numbers of claims. *Id.* at introduction. Indeed, EPA's reluctance to review claims was related to the scale of the problem. *Id.* at 32-33 (noting that a 1992 EPA study "indicated that problems with inappropriate claims were extensive"). If fully implemented, EPA's new policy, under which it engages in a general practice of reviewing confidentiality claims for chemical identities in health and safety studies and data from those studies, and by which it announced that it does not expect such chemical identities to be entitled to confidential treatment unless they explicitly contain process information or reveal portions of a mixture, will begin to bring practice into line with the statute.

Notably, absent specific chemical names, the information in health and safety studies can be rendered all but useless to the scientific community, chemical users, state, Tribal and

local government officials, and the public. Consider, for example, the health and environmental risk information provided in Section 8(e) substantial risk notices. These notices describe health and safety studies or data that reasonably support the conclusion that certain chemical substances or mixtures present a substantial risk of injury to health or the environment. 15 U.S.C. § 2607(e).[7] Among other health and environmental risks, Section 8(e) notices describe studies and other evidence linking particular chemicals with cancer, reproductive and developmental abnormalities, mutagenesis, and neurotoxicity. Though all Section 8(e) notices are posted on EPA's website, companies have frequently asserted that the names of the chemicals at issue constituted CBI, and EPA historically accepted these claims without question unless someone sought information through a request under the Freedom of Information Act (FOIA), 5 U.S.C. § 552(a). Thus chemical names were – and continue to be – redacted from a significant number of Section 8(e) notices posted on EPA's website, including a majority of the chemicals covered by the notices received during some months. *See, e.g., TSCA Section 8(e) Notices*, EPA, http://www.epa.gov/opptintr/tsca8e/pubs/8emonthlyreports/2009/8enov2009.html (last visited Feb. 28, 2012). EPA statistics indicate that for fiscal years 2006 through 2009, nearly 70% of Section 8(e) notices submitted to EPA contained CBI claims, and for more than 40% of them the chemical identity was specifically claimed as CBI. EPA, TSCA Statistics for Congressional Briefing (Documents Received from FY 06 through FY 09)(received from EPA by OMB Watch pursuant to FOIA request) (undated).

As a report by the Congressional Research Service stated, the value of 8(e) submissions and EPA's website making the studies available to the public "is greatly reduced by the confidentiality claims of the submitters: in most cases, the identity of the chemical is concealed." Linda-Jo Schierow, Cong. Research Serv., CRS RL 34118, The Toxic Substances Control Act (TSCA): Implementation and New Challenges 13 (Jul. 28, 2009).

Consider, for example, the information provided in a "Company Sanitized" Section 8(e) notice about an "Optionally Substituted Aromatic Substance." *See Notice in Accordance with Section 8(e): Results of a Developmental Toxicity Screening Study in Wistar Rats with Optionally Substituted Aromatic Substance*, BASF, 8EHQ-09-17748, at 1 (Nov. 25, 2009), http://www.epa.gov/opptintr/tsca8e/pubs/8ehq/2009/nov09/8ehq_1109_17748a.pdf. This notice reported on toxicity findings relevant to fetal development, including the following:

- Statistically significantly reduced mean fetal weights (70%), i.e. males (71%), females (69%), compared to the control group (set to 100%)

[7] 15 U.S.C. § 2607(e) provides:

> Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

- Two fetuses with cleft palate
- Four fetuses with anasarca
- Fourteen fetuses with malrotated limbs

Id. at 2. Despite the disconcerting information about the effects associated with the "Optionally Substituted Aromatic Substance," this notice is useless because the chemical identity of the substance has been redacted.

Similarly, consider another self-titled "Sanitized Version" of a Section 8(e) notice dated November 23, 2009, which does not disclose the identity of the chemical that is the subject of the notice. The filing reports on the results of an acute eye irritation test in rabbits with "a Formulation Containing Two Active Ingredients; (1) Substituted Nitrogen Containing Heterocycle and (2) Substituted Epoxide," and indicates that "[t]he test substance is a crop protection formulation." *Notice in Accordance with Section 8(e): Results of an Acute Eye Irritation Test in Rabbits with a Formulation Containing Two Active Ingredients; (1) Substituted Nitrogen Containing Heterocycle, and (2) Substituted Epoxide*, BASF, 8 EHQ-1109-17747A, at 1 (Nov. 23, 2009), http://www.epa.gov/opptintr/tsca8e/pubs/8ehq/2009/nov09/8ehq_1109_17747a.pdf. Among other things, the notice reports the following:

> Slight to moderate corneal opacity, moderate iritis, slight to severe conjunctival redness, slight to moderate conjunctival chemosis and slight to severe discharge were observed in the animals during the course of the study. Additional findings like contracted pupil, marginal vascularization of the cornea in a circumscribed area or circular as well as vascularization into the central part of the cornea in a circumscribed area and injected scleral vessels in a circumscribed area or circular were noted in the animals during the observation period.

Id. Indeed, findings were significant; the notice concludes: "Considering the described ocular reactions as well as the average score for irritation, the formulation substance causes serious eye damage under the test conditions chosen." *Id.* at 2. The public was thus on notice of danger from an unspecified "crop protection formulation," but the notice was otherwise of severely limited utility. *See id.* at 1; *see also* Richard A. Denison, *Hiding a Toxic Nanomaterial's Identity: TSCA's Disappearing Act* (July 14, 2009), http://blogs.edf.org/nanotechnology/2009/07/14/hiding-a-toxic-nanomaterials-identity-tscas-disappearing-act/ (discussing CBI claim for a material generically named "Carbon Nano Tube").[8]

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[8] In another Section 8(e) notice dated April 15, 2010, the identity of the company submitting the notice, the "subject chemical," and "alternative name" were all redacted. *TSCA Section 8(e) Substantial Risk Notification*, 8 EHQ 0410-17890A, at 1 (Apr. 15, 2010), http://www.epa.gov/opptintr/tsca8e/pubs/8ehq/2010/apr10/8ehq_0410_17890a.pdf (company name and identification of chemical omitted). The text of the letter is replete with deletions, rendering the notice essentially useless as a means of informing the public of health and safety concerns:

The identity of the chemicals in health and safety studies submitted to EPA pursuant to Section 5 PMN requirements is similarly crucial information necessary for the interpretation of the studies and of great interest to the public.[9] For example, even before distribution for commercial purposes, workers may well be exposed to a new chemical. If a labor union is concerned about exposure and takes the step of arranging for biomonitoring of workers in a facility making a new chemical, the ability to determine whether there is – and prove the origin of – exposure to the chemical requires knowledge of its specific chemical identity. To present evidence that workers are being exposed to a chemical that belongs to the class of chemicals identified by reference to a generic name would likely lead to disputes, especially if the company also produces other structurally related chemicals. More generally, workers should not have to rely exclusively on their employers' or EPA's knowledge of specific chemical identity, and should have the ability independently to assess their potential exposure to a new chemical.

In addition, there may be environmental releases of a chemical even before commercial production begins. If concerned citizen groups or environmental researchers arrange for environmental monitoring, for example, in the vicinity of a facility making a chemical, they would similarly need to know specific chemical identity in order to monitor for it, and the same concerns would arise if only access to a generic name were provided.

> [ ] has been made aware of preliminary findings from a second 28-day inhalation study in the rat. The dose levels of [] employed were 0,500, 1500, 5000, and 15000 ppm. These dose levels were selected on the basis of the first 28-day inhalation study reported to the EPA under Section 8(e) of TSCA in a letter dated August 26, 2009. [ ] believes the results of the second 28-day study to be reportable under the established criteria for notification of substantial risk under TSCA Section 8(e).
>
> Groups of 10 male and 10 female Wistar rats were exposed to [ ] by inhalation(nose only) at levels of 0, 500, 1500, 5000 and 15000 ppm for 6 hours per day, 5 days per week for four weeks.
>
> An incidence of minimal to moderate myocardial focal/multifocal inflammation, accompanied by minimal to moderate vacuolation and/or myofibre degeneration was observed in all groups of exposed rats….

Id. at 1. Again, absent chemical identity, significant findings are rendered of limited or no utility for the public.

[9] Concerns about the impact of revealing chemical identities along with the name of the manufacturer or distributor on the competitive position of a manufacturer or distributor can be reduced through the mechanics of disclosure. If releasing chemical identity together with the name of the company would affect the manufacturer or processor's competitive position, EPA can disclose chemical identity in the study but redact company identifying information.

Test marketing of products containing chemicals also presents the possibility of exposures even if only on a limited scale. While the manufacturer would have to apply for a test marketing exemption (TME) pursuant to 40 C.F.R. § 720.38, it may well be granted on the basis of a limited review by EPA. All of the same rationales discussed above for the need to know specific chemical identity, and the same concerns would arise if only access to a generic name were provided.

Finally, new chemicals are frequently developed to replace existing ones that have been shown to be risky. Recent examples include the introduction of substitute flame retardants to replace polybrominated diphenyl ethers (PBDEs) and substitute fluorotelomers to replace those that break down into perfluorooctanoic acid (PFOA). Often in such cases, structurally similar chemicals are used as the substitutes. *See, e.g.*, Press Release, DuPont, New DuPont™ Capstone™ for Repellents and Surfactants Deliver Maximum Performance, Minimal Environmental Footprint (Mar. 31, 2008), http://www2.dupont.com/Capstone/en_US/assets/downloads/final_press_release_english_3_20_2008.pdf. This creates more than a theoretical concern that the substitutes could pose the same or similar risks. There is a strong, legitimate public interest in having access to robust health and safety information for such chemicals *before* they enter widespread use.

EPA's 2010 CBI policies and the Proposed Regulation are also consistent with this Administration's commitment to transparency and scientific inquiry. Executive Order 13563 directs agencies "[w]here relevant, feasible, and consistent with regulatory objectives, and to the extent permitted by law" to "identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public. These approaches include warnings, appropriate default rules, and disclosure requirements as well as provision of information to the public in a form that is clear and intelligible."[10] Enforcement of TSCA Section 14(b), providing for the disclosure of chemical identity in the context of health and safety studies unless the information would reveal process or portion information, promotes informed consumer choice and makes information accessible to the public.

Disclosure also serves to ensure that health and safety studies are made available to the scientific community and furthers scientific inquiry and the goal of scientific integrity. At a 2009 National Academy of Sciences Annual Meeting, President Obama affirmed this Administration's interest in "restoring science to its rightful place." He stated,

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[10] Exec. Order No. 13563, 76 Fed. Reg. 14, Sec. 4 (Jan. 21, 2011), *available at* http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf; *see also* Executive Office of the President, Memorandum for the Heads of Executive Departments and Agencies: Informing Consumers Through Smart Disclosure (Sept. 8, 2011), http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/informing-consumers-through-smart-disclosure.pdf.

> Under my administration, the days of science taking a back seat to ideology are over. Our progress as a nation –- and our values as a nation –- are rooted in free and open inquiry. To undermine scientific integrity is to undermine our democracy. It is contrary to our way of life.

Office of the Press Secretary, Remarks by the President at the National Academy of Sciences Annual Meeting (Apr. 27, 2009), http://www.whitehouse.gov/the_press_office/Remarks-by-the-President-at-the-National-Academy-of-Sciences-Annual-Meeting.[11] Shielding chemical identity in health and safety studies from public disclosure is in conflict with both the terms of TSCA Section 14(b) and the affirmation of free and open inquiry.

II. Disclosure of Chemical Identity Information in Health and Safety Studies is Consistent with TSCA Section 14(b)

ACC argues that EPA incorporates a balancing test, and that the interest in disclosure should be weighed against the interest in protecting trade secrets. *See* ACC White Paper at 26-28. Indeed, Section 2 of TSCA does require that, in implementing the provisions of TSCA, the Administrator "shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take." 15 U.S.C. § 2601(c). However, Section 14 of TSCA does not call for a balancing test and contains explicit language governing the disclosure of information reported to EPA pursuant to the provisions of TSCA.

Section 14(a) contains a general provision governing disclosure of data outside of the context of health and safety studies, which protects information that is exempt from disclosure under the Freedom of Information Act as a trade secret. *See* 15 U.S.C. § 2613(a). TSCA Section 14(b)(1) specifically provides that health and safety studies *and data* from health and safety

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[11] *See also* EPA, Scientific Integrity Policy, at 5, http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_20120115.pdf (last visited Feb. 28, 2012), which states:

> Scientific research and analysis comprise the foundation of all major EPA policy decisions. Therefore, the Agency should maintain vigilance toward ensuring that scientific research and results are presented openly and with integrity, accuracy, timeliness, and the full public scrutiny demanded when developing sound, high-quality environmental science. This policy [EPA's Scientific Integrity Policy] is intended to outline the Agency's expectations for developing and communicating scientific information to the public, to the scientific community, to Congress, and to the news media by further providing for and protecting the EPA's longstanding commitment to the timely and unfiltered dissemination of its scientific information – uncompromised by political or other interference. This policy recognizes the importance of, and the need to foster a culture of, openness regarding the results of research, scientific activities, and technical findings. To that end, the EPA strongly encourages and supports transparency and active, open communications through various forms....

studies are not entitled to confidential treatment, with two significant and explicit exceptions for process and portion information. *See* 15 U.S.C. § 2613(b)(1) (emphasis added). Section 14(b)(1) provides:

> (b) Data from health and safety studies
> (1) Subsection (a) does not prohibit the disclosure of –
> (A) any health and safety study which is submitted under this chapter with respect to –
> (i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution, or
> (ii) any chemical substance or mixture for which testing is required under section 2603 of this title or for which notification is required under section 2604 of this title, and
> (B) any data reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

15 U.S.C. § 2613(b)(1). The process or portion exceptions are explicit:

> This paragraph does not authorize the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

Id. By its very terms, Section 14(b) protects data revealing process or portion information but does not provide similar protection for chemical identity outside of those contexts. Had Congress intended to exempt chemical identity from disclosure, Section 14(b) could have included this exemption along with the process and portion exceptions, but such language is noticeably absent.[12] Indeed, the process and portion exceptions are premised on an understanding that, more generally, chemical identity is not shielded from disclosure.

TSCA Section 3(6) broadly defines the phrase "health and safety study" to mean:

> Any study of any effect of a chemical substance or mixture on health or the environment or on both, *including underlying data* and epidemiological

[12] Had Congress intended to carve out a larger exception to the disclosure of information in health and safety studies, it could have done so clearly and expressly. *See Meghrig v. KFC Western, Inc.*, 516 U.S. 479, 485 (1996) (finding omission of language by Congress in CERCLA significant); *FCC v. NextWave Pers. Commc'ns, Inc.*, 537 U.S. 293, 302 (2003) (finding that when Congress intended to create exceptions to the requirements of bankruptcy law, "it had done so clearly and expressly").

> studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this Act.

15 U.S.C. § 2602(6) (emphasis added).[13] Consistent with that broad definition, EPA's regulations define "health and safety study" as including "[a]ny data that bear on the effects of a chemical substance on health or the environment" and specifically confirm that "[c]hemical identity is part of, or underlying data to, a health and safety study." 40 C.F.R. § 716.3; *see also id.* § 720.3(k) ("Chemical identity is always part of a health and safety study.") Clearly, the identities of the chemicals in health and safety studies are part of the data that give meaning to the results. As such, chemical identity associated with a health and safety study is not entitled to confidentiality unless disclosure would reveal process or portion information.

A. Section 5 PMN Disclosure Provisions are "Subject to" the Provisions of Section 14 and, Thus, Chemical Identity Information in the Context of Health and Safety Studies Submitted to EPA Pursuant to Section 5 is Subject to Disclosure

ACC asserts that data from health and safety studies submitted to EPA pursuant to Section 5 of TSCA is subject to protection as trade secrets or CBI and that Section 5(d)(2) "specifically endorses disclosure of generic names" in the context of PMNs. ACC White Paper at 1-2. These arguments are mistaken.

TSCA Section 5 requires manufacturers, importers, and processors to notify EPA at least 90 days prior to producing or otherwise moving a new chemical into commerce into the United States or when planning a significant new use of the chemical. 15 U.S.C. § 2604(a)(1)((B). Such manufacturers, importers, and processors are required to submit to EPA any information or test data that is known to or reasonably ascertainable by them, or in their possession, that might be useful to EPA in evaluating the risks of the chemical for human health and the environment. 15 U.S.C. § 2604; *see also* Linda-Jo Schierow, Cong. Research Serv., CRS RL 31905, The Toxic Substances Control Act (TSCA): A Summary of the Act and Its Major Requirements 3-4 (February 2, 2010). ACC relies on two provisions, Sections 5(b)(3) and 5(d)(2), which it claims limit disclosure of chemical identity based on trade secrets or CBI claims and, in the case of Section 5(d)(2), "endorses disclosure of generic names instead of confidential identities where `required in the public interest.'" ACC White Paper at 2. The text of both of these provisions,

[13] The definition of "health and safety study" provided by TSCA Section 3(6) encompasses outcomes and underlying data that bear on the content of the study, including chemical identity. As a study prepared for EPA back in 1992 noted, "It is unlikely that any reputable health or environmental scientist could be found who would argue that it is ever the case that chemical identity is unnecessary to interpret health and safety data." Sheila Ferguson, et al., EPA-HQ-OPPT-2002-0054-0074, Influence of CBI Requirements on TSCA Implementation, Hampshire Research Assocs. (Mar. 1992), at 24. Chemical identity is thus distinguishable from information about the manufacturer or distributor, such as its finances, which arguably would not usually be considered "data" and may be extraneous to interpretation of the health and safety study.

however, contains explicit language clarifying that disclosure requirements are "subject to section 2613" – in other words, subject to the protection of Section 14(a) and subject to the disclosure requirements for health and safety studies in Section 14(b). Specifically, the relevant portions of Section 5 provide:

> (b)(3) Data submitted under paragraph (1) or (2) shall be made available, *subject to section 2613, of this title,* for examination by interested persons.
>
> (d)(2) *Subject to section 2613 of this title*, … the Administrator shall publish in the Federal Register a notice which –
>
> > (A) identifies the chemical substance for which notice or data has been received;
> > (B) lists the uses or intended uses of such substance; and
> > (C) in the case of the receipt of data under subsection (b) of this section, describes the nature of the tests performed on such substance and any data which was developed pursuant to subsection (b) of this section or a rule under section 2603 of this title.
>
> A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

15 U.S.C. § 2604(b)(3), (d)(2) (emphasis added). Thus, Section 5(b)(3) mandates that the EPA make available data submitted pursuant to Section 5(b)(1) and (2), *subject to* the disclosure requirements of Section 14. Similarly, Section 5(d)(2) mandates that EPA publish information in the Federal Register *subject to* the disclosure requirements of Section 14. As discussed above, Section 14(b) provides for the disclosure of chemical identity and other data in health and safety studies unless such disclosure would reveal process or portion information.

Although Section 5(d)(2) does contain language endorsing the disclosure of generic names in PMNs published in the Federal Register, generally, this provision is explicitly *subject to* the more specific mandate in Section 14(b) *if the information is part of a health and safety study*.

Assuming for the sake of argument that we can ignore the language subjecting Section 5(d)(2) to the disclosure requirements of Section 14 and that it is plausible to interpret the specific language requiring EPA to identify chemical substances by generic class as carving out an exception to Section 14(b), this exception would apply only to the disclosure of chemical identity in health and safety studies received pursuant to Section 5 required to be made public

by EPA.[14] By its own terms, the provision only applies to the identification of chemical substances in a Section 5 notice. 15 U.S.C. § 2604(d)(2) ("*A notice under this paragraph* respecting a chemical substance shall identify the chemical substance by generic class….") (emphasis added). Moreover, similar language does not appear in Sections 4 or 8 of TSCA, and the provision cannot be read as a broad amendment to Section 14(b).

B. Section 4's Test Data Notice Provisions are also "Subject to" the Provisions of Section 14 and, Thus, Chemical Identity Information in the Context of Health and Safety Studies is Subject to Disclosure

ACC inexplicably argues that disclosure of data in health and safety studies pursuant to Section 4(d), which sets forth the requirements for providing notice of the receipt of test data, is also subject to protection as trade secrets or CBI. ACC White Paper at 2. This interpretation defies the language of Section 4(d) and canons of statutory construction.

Specifically, TSCA Section 4(d) provides:

> (d) Notice
> Upon the receipt of any test data pursuant to a rule under subsection (a) of this section, the Administrator shall publish a notice…. *Subject to section 2613 of this title*, each such notice shall (1) *identify the chemical substance or mixture for which data have been received*; (2) list the uses or intended uses of such substance or mixture and the information required by the applicable standards for the development of test data; and (3) describe the nature of the test data developed. *Except as otherwise provided in section 2613 of this title, such data shall be made available by the Administrator for examination by any person.*

15 U.S.C. § 2603(d) (emphasis added).

Notably, this provision states explicitly that it is subject to the mandates of TSCA Section 14, both the protections afforded and the disclosure requirements of Section 14 (a) and (b). Section 4(d) refers to Section 14 twice: first, to establish that the notice requirement, generally, is subject to Section 14, and then subsequently, as a limitation on data to be made available for examination. *See id.*

Moreover, Section 4(d) explicitly requires that each notice "shall" "identify the chemical substance or mixture for which data have been received." 15 U.S.C. § 2603(d). Finally, to the

[14] To ignore the "subject to" clause, however, would be to violate the basic principle of statutory construction that calls for giving effect, where possible, to every clause and word of a statute and to avoid rendering statutory language superfluous. *See Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 112 (1991); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 63 (2002).

extent that ACC has argued that the language in Section 5 regarding generics is relevant to data in health and safety studies, it is significant that Section 4(d) contains no such provision.[15] ACC suggests that rejected language in a 1975 House bill, H.R. 7664, which mirrored the language that ultimately appeared in Section 5(d)(2) demonstrates that Section 4(d) "was intended to protect trade secret or confidential identities from disclosure." ACC White Paper at 12. To the contrary, "'[W]here Congress includes particular language in one section of a statute but omits it in another . . . it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'" *Keene Corp. v. United States*, 508 U.S. 200, 208 (1993) (citting Russello v. United States, 464 U.S. 16, 23 (1983)).[16]

III. Disclosure of Chemical Identity Information in Health and Safety Studies is Consistent with Congressional Intent

TSCA was enacted in 1976, in an era when policy makers were paying increasing attention to the risks that toxic substances posed to human health and the environment. *See* David Markell, *An Overview of TSCA, its History and Key Underlying Assumptions, and its Place in Environmental Regulation*, 32 Journal of Law & Policy 333, 338-340 (2010). Other laws in place at the time that addressed the dangers of chemical substances included the Clean Air Act, the Federal Water Pollution Control Act, the Occupational Safety and Health Act, and the Consumer Product Safety Act. *See* S. Rep. No. 94-698, at 1 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491, 4491. Yet the statutes in place prior to TSCA's enactment left a number of regulatory gaps.

Prior to TSCA, the law failed to provide a way to discover the adverse health and environmental effects of chemical substances before they were manufactured. *See id.* The government's only response to chemical dangers was to regulate after manufacturing began. *See id.* at 5. The 1971 Council on Environmental Quality (CEQ) Report, Toxic Substances, which set the foundation for TSCA legislation, noted that then current laws were inadequate to control the dangers of toxic substances and that media-based pollution laws did not adequately account for a person's total exposure to chemicals. *See* U.S. Council on Environmental Quality, Toxic Substances at *v (Apr. 1971); Markell, *An Overview of TSCA*, at 346. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which was essentially rewritten in 1972 by the Federal Environmental Pesticide Control Act (FEPCA), addressed chemical dangers prior to the manufacturing process, but covered only a small portion of the total number of potentially toxic

[15] If, however, test data developed pursuant to a Section 4 rule is received by EPA in connection with a PMN or SNUN requirement under Section 5, such data would also be subject to Section 5(d)(2) disclosure requirements.

[16] *See also Pacific Gas & Elec. Co. v. Energy Res. Conserv. & Dev. Comm'n*, 461 U.S. 190, 220 (1983) ("While we are correctly reluctant to draw inferences from the failure of Congress to act, it would, in this case, appear improper for us to give a reading to the Act that Congress considered and rejected"); *Doe v. Chao*, 540 U.S. 614, 622 (2004) (finding significant evidence "that Congress cut out the very language in the bill" that would have authorized the presumed damages being urged on the Court).

substances and did not deal with all uses of a substance that may produce toxic effects. *See* U.S. Council on Environmental Quality, Toxic Substances at *v (Apr. 1971); 7 U.S.C. § 136 *et seq*.

TSCA was enacted to close these regulatory and information gaps. *See* S. Rep. No. 94-698, at 1 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491, 4491. Its primary purpose is to "prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances." *Id*. at 1; *see also* Markell, *An Overview of TSCA*, at 346. The 1977 CEQ Annual Report stated that the major accomplishment of TSCA "is that it gives the government broad authority to control the production, distribution, and use of all potentially hazardous chemicals. It provides for testing of suspect chemicals before they become widely used and economically important. It emphasizes collection of information and freedom of access to research data so that the scientific community can note and assess potential problems." Council on Environmental Quality, Eighth Annual Report of the Council on Environmental Quality 1-3 (1977). The 1978 CEQ Report summarized TSCA's role as giving the government "a new mandate and broad new authority to gather information on the potential of chemicals to damage human health and the environment . . . The result is more awareness on the part of government, industry, scientists, and the public of the problems of toxic chemicals . . . ." Council on Environmental Quality, Ninth Annual Report of the Council on Environmental Quality 178 (1978).

ACC's argument that statements made during the legislative process leading to TSCA in 1975-1976 support continued protection of chemical identity information relies on imprecise readings of the legislative record. In fact, the legislative record makes clear that Congress heard testimony regarding CBI issues, and that TSCA was intended to provide for the disclosure of chemical identity within the context of health and safety studies unless such disclosure would reveal process or portion information.

ACC often conflates arguments made for the protection of formulae, process, or portion information with the question whether chemical identity should be disclosed. For example, ACC quotes the Statement of Anita Johnson from the Public Citizen Health Research Group (ACC White Paper at 19), who expressed support for protecting secret formulas and secret manufacturing methods as trade secrets, but advocated for disclosure of health and safety data. *See Hearing on H.R. 7229, H.R. 7548, and H.R. 7664 before the House Subcomm. on Consumer Protection and Finance of the Comm. on Interstate and Foreign Commerce,* 94th Cong. 355 (1975) (statement of Anita Johnson, Public Citizen Health Research Group). Yet nothing about that statement is inconsistent with allowing the disclosure of chemical identities, since it only speaks to protecting formulas and manufacturing methods. Read in its entirety, Ms. Johnson's statement expresses deep concern for public health and the desire for complete disclosure of health and safety data, other than information disclosing processes and formulas, reflecting the language of TSCA §14. *See id.;* 15 U.S.C. §2613(b)(1)(B). ACC also quotes Dr. Sidney Wolfe who stated that legitimate trade secrets should not be disclosed, but who also testified that health and safety studies are not trade secrets. ACC White Paper at 19; *Hearing on S. 776 Before the Senate Subcomm. on the Environment of the Comm. on Commerce,* 94th Cong. 168-169 (1975)

(statement of Dr. Sidney Wolfe, Health Research Group). Dr. Wolfe's testimony is an example of testimony before Congress in support of disclosure of chemical identity in the context of health and safety information. Similarly, ACC quotes Jacqueline Warren from the Environmental Defense Fund as suggesting that detailed information about chemical identity might qualify as trade secrets. ACC White Paper at 19; *Hearing on S. 776 Before the Senate Subcomm. on the Environment of the Comm. on Commerce*, 94th Cong. 171 (1975) (statement of Jacqueline Warren, Environmental Defense Fund). A full reading of the testimony, however, makes clear that the discussion distinguished between "detailed" information that would disclose information about the manufacture of chemicals and the importance of disclosing chemical identity to the public. *Hearing on S. 776 Before the Senate Subcomm. on the Environment of the Comm. on Commerce*, 94th Cong. 171 (1975) (statements of Jacqueline Warren, Environmental Defense Fund, and Dr. Albert Fritsch, Center for Science in the Public Interest).[17]

ACC states that a 1975 report released by the National Academy of Sciences recommended that proprietary data be protected from disclosure unless essential to evaluating a hazard of the chemical. ACC White Paper at 19; National Academy of Sciences, Decision Making for Regulating Chemicals in the Environment 28 (1975), *available at* http://books.google.com/books?id=1zArAAAAYAAJ&printsec=frontcover&dq=%22Decision+Making+for+Regulating+Chemicals+in+the+Environment+%22&source=bl&ots=0KpnIvNpTP&sig=pNWX4LW5HFJCqxwSvUYPUrKiHY&hl=en&ei=gfexTZTZOKbf0QHxtqGKCQ&sa=X&oi=book_result&ct=result&resnum=1&ved=0CBoQ6AEwAA. Yet ACC fails to mention that proprietary data in the report are defined as use data, such as to whom the chemical is sold, and not chemical identity. *See id.* The report specifically states that intrinsic toxicological properties of a given substance are non-proprietary data, a definition that would support the disclosure of chemical identity in health and safety studies. *See id.*

More significantly, TSCA's legislative history demonstrates Congressional intent to require disclosure of chemical identity in the context of health and safety studies, while protecting CBI that contains portion and process information. In House Conference report 94-1679, the conference substitute for the House and Senate bill language specifically provided that "disclosure of any health and safety study or information from such a study on any substance or mixture which is already being distributed or for which testing is required under section 4 or

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[17] ACC also quotes Orin Smith from M&T Chemical Co., who states that the "chemical entity's molecular structure, proposed usage and amounts to be manufactured should not be published for all to see." ACC White Paper at 19; *Hearing on* S. 776 *Before the Senate Subcomm. on the Environment of the Comm. on Commerce*, 94th Cong. 121 (1975) (statement of Orin Smith, M&T Chemical Co.). It is unsurprising that a representative from a chemical company argued for protection of chemical identities in health and safety studies. Such isolated statements at the particular Hearings should be examined cautiously, as they are merely arguments before the House and Senate committees and do not reflect the committees' opinions. Although reference to legislative history for background and context can be helpful, isolated statements by individual members of Congress or even committees, much less lobbyists, "cannot substitute for a clear expression of legislative intent at the time of enactment." *See Southeastern Community College v. Davis*, 442 U.S. 397, 411 n.11 (1979).

for which notification is required under section 5, is not prohibited. Data in such a study which disclosed manufacturing *processes* or the *proportions* of a mixture may not be disclosed if such *processes* or *proportions* would otherwise be entitled to protection from disclosure." H.R. Rep. No. 94-1679, at 36 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4539,4576 (emphasis added). The report specifies that manufacturing processes and the proportions of chemicals in a mixture may not be disclosed, consistent with the language of TSCA section 14(b)(1)(B). *See id.; see also* 15 U.S.C. § 2613(b)(1)(B).

Furthermore, TSCA House Committee Report 94-1341 stated "in referring to data 'disclosing the portion of the mixture comprised by any of the chemical substances in the mixture,' the Committee intends to protect confidential trade secret information respecting the specific formulation of a mixture. However, the Committee does not intend to prohibit the Administrator from disclosing the *chemical substances* comprising the mixture by their order of quantity in the mixture." H.R. Rep. No. 94-1341, at 51 (1976), Legis. Hist. at 458 (emphasis added).

A. ACC's Reliance on FIFRA is a Red Herring: FIFRA's Disclosure Terms are Inapposite

ACC's argument about the relevance of FIFRA to an understanding of TSCA suffers from some of the same obfuscation found elsewhere in the White Paper: perhaps most fundamentally, ACC conflates chemical identity with formulae, process or portion information. *See, e.g.,* ACC White Paper at 23 ("Several provisions explicitly protected confidential *formula* information, including the *identity* of confidential inerts….") (emphasis added). The White Paper's core argument, though, is that TSCA's treatment of trade secrets was modeled after FIFRA. ACC White Paper at 15-22. ACC contends that the disclosure requirement in TSCA Section 14(b) "did not relate to proprietary data" in health and safety studies, "such as trade secret or confidential chemical identities, which under FIFRA were protected." ACC White Paper at 15. This argument is patently misguided: Section 14(b) clearly relates to information that would otherwise have been considered a trade secret or CBI. This was the very reason for Section 14(b). Moreover, FIFRA itself provides for the release of the identity of active ingredients. 7 U.S.C. §§ 136(n)(defining "ingredient statement" to include the name and percentage of each active ingredient), (q)(2)(establishing that a "pesticide is misbranded if – (A) the label does not bear an ingredient statement…."). Indeed, nothing in the legislative history of TSCA suggests that TSCA's disclosure requirements concerning health and safety studies should be read in light of FIFRA, and a comparison of the language in the two statutes reflects significant and material distinctions. ACC's focus on FIFRA is a red herring.

FIFRA and TSCA reflect different approaches to questions of confidentiality. The statutes were each intended to address different circumstances and, with each, Congress offered solutions tailored to the purpose of the statute. For example, TSCA does not differentiate between active and inert chemicals, and specifies that information in health and safety studies regarding the "portion of the mixture" or the manufacturing process of the chemical may not be

revealed. *See* 15 U.S.C. § 2613(b)(1)(B). FIFRA, on the other hand, requires that active ingredients be disclosed on product labels, together with their percentage by weight, and only protects from disclosure the identity of inert ingredients. *See* 7 U.S.C. §§ 136(q), h(d)(1)(A)-(C); 40 C.F.R. § 156.10(g). Since under FIFRA the active ingredients of pesticides are already revealed to the public, they face no confidentiality or trade secret issues. For inert ingredients, FIFRA labeling regulations require a listing of the total percentage by weight of all inert ingredients. *See id.*

Moreover, a comparison of the language in FIFRA and TSCA shows that Congress knew how to use explicit language to protect chemical identities from being disclosed, and chose not to do so in the context of data submitted to EPA under TSCA as part of health and safety studies. TSCA was enacted a few years after the FEPCA amended FIFRA, although the first TSCA bill was introduced in 1971 while the FIFRA amendments were still being considered. *See* S. Rep. No. 92-970 (1972), *reprinted in* 1972 U.S.C.C.A.N. 4092; *Toxic Substances Control Act of 1971 and Amendment. Part 1: Toxic Substances*, *Hearing Before the Senate Committee on Commerce, Science, and Transportation*, 92nd Cong. (1971). FIFRA was subsequently amended by the Federal Pesticide Act of 1978, which provided that health and safety studies submitted under FIFRA should be publicly disclosed unless information in the study revealed the "manufacturing or quality control processes," methods for testing the quantity of deliberately added inert ingredients, or the "identity or percentage quantity of any deliberately added inert ingredient of a pesticide." *See* Federal Pesticide Act of 1978, Pub. L. No. 95-396 (1978) § 15(2); 7 U.S.C. § 136h(d). Section 10(d)(1)(C) of FIFRA specifically protects from disclosure any information that discloses the *identity* or percentage quantity of any deliberately added inert ingredient. The word "identity" was used to specify that not only was the percentage quantity of the inert ingredient a trade secret but also the inert ingredient's identity. TSCA section 14(b)(1)(B) notably leaves out the word "identity" and only specifies that information revealing manufacturing "processes" and "portion" of a mixture be protected from disclosure. The difference in the wording as to trade secret protection for health and safety studies is especially revealing given the relatively concurrent consideration and passage of amendments to FIFRA and TSCA. Congress evidently knew full well how to protect chemical identities from disclosure. It chose to do so with inert ingredients in FIFRA Section 10, and it chose not to do so with chemical identity of substances in health and safety studies in TSCA Section 14. *See* 7 U.S.C. § 136h(d)(1)(A)-(C); 15 U.S.C. § 2613(b)(1)(B).

B. ACC's Reliance on a Range of Provisions in Other Environmental Laws is Misplaced and Unpersuasive

Grasping at straws, ACC argues further that TSCA should also be read in light of the Emergency Planning and Community Right-to-Know Act (EPCRA), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), and the Superfund Amendments and Reauthorization Act (SARA). ACC White Paper at 22-26. Yet EPCRA was enacted in October of 1986, CERCLA, commonly known as Superfund, was enacted in December of 1980, and SARA amended CERCLA in October of 1986. *See* 42 U.S.C. § 11001 *et*

seq. (1986); 42 U.S.C. § 9601 *et seq*. (1980). All of these statutes were enacted significantly later than TSCA and focus on the release of chemicals into the environment from individual facilities rather than manufactured products entering into commerce. *See id.* They do not shed light on Congressional intent in 1976 and should not be used as guidance for interpreting TSCA provisions.

IV. Generic Names Are Neither a Permissible Substitute for Disclosure Required by TSCA Section 14(b) Nor Do They Provide Sufficient Information to the Public

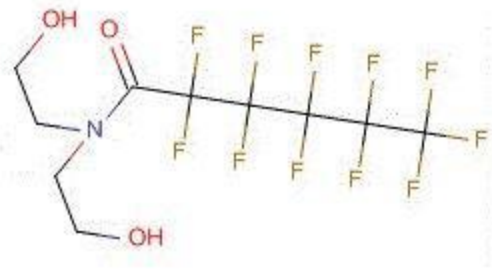
Section 14(b) does not contemplate the substitution of generic names for chemical identity in health and safety studies unless otherwise confidential chemical identity would reveal process or portion information. Neither do generic names provide sufficient information to the public. Incredibly, ACC seems to argue that using generic names will enhance access to information, suggesting that a search using a generic name will produce more information about the toxicology of a chemical than one using a CAS number or name. ACC White Paper at 30. Of course, nothing precludes a researcher from searching for the generic as well as the chemical name, though the reverse is not true. By definition, having only the generic name does not allow the researcher to identify and search for information about the specific chemical. Even with a generic name policy in place, the substitution of generic names creates a barrier to the flow of information and limits the possibility of understanding available health and safety studies.

To illustrate how the use of generic names obscures rather than illuminates information essential to the public's ability to understand and use health and safety information, we will examine: A) EPA's current guidance on selection of generic names; B) examples of actual generic names chemical manufacturers have provided when submitting "substantial risk" notices to EPA as required under TSCA Section 8(e) and PMNs, and that EPA has in turn provided to the public; and C) an example of a generic name of a chemical for which a PMN was filed in the past that included health and safety studies, the specific chemical identity of which EPA has recently declassified pursuant to its 2010 policies.

A. EPA's Current Guidance on Selection of Generic Names

EPA's current guidance document, "Generic Names for Confidential Chemical Substance Identity," issued in 1985, provides examples of "acceptable" generic names to be used in lieu of a specific chemical identity.[18] One example is a set of "acceptable" generic names for the specific chemical depicted below: 2,2,3,3,4,4,5,5,6,6,6—Undecafluoro—N,N—bis(2—hydroxyethyl)hexanamide.

[18] EPA, TSCA Inventory, 1985 Edition, Appendix B: Generic Names for Confidential Chemical Substance Identities, http://www.epa.gov/oppt/newchems/pubs/genericnames.pdf (last visited Feb. 29, 2010).



Each of the "acceptable" generic names EPA allows for this chemical would encompass an exceedingly high number of potential chemical substances. For example, EPA suggests using a generic name that masks the fluorine (F) atoms in this substance (*i.e.*, N,N—Bis(2—hydroxyethyl), 2,2,3,3,4,4,5,5,6,6,6-undecasubstituted hexanamide). Such a generic name would include chemical substances with any possible combination of halogen atoms – bromine, chlorine, etc., replacing the fluorine atoms in each of the 11 positions shown above. This would theoretically include millions of distinct chemical compounds. Research has clearly shown that different forms of a chemical substance containing different types of halogen atoms can have very different toxicological profiles and environmental and biological fate. *See, e.g.*, EPA, Polybrominated Diphenyl Ethers (PBDEs) Action Plan (Dec. 30, 2009), http://www.epa.gov/oppt/existingchemicals/pubs/pbdes_ap_2009_1230_final.pdf (variation in toxicity and environmental fate among PBDEs based on extent of bromination). In order to have a clear understanding of the potential toxicity of a chemical substance it is essential to know the types of halogen atoms present.

Another generic name EPA allows for this chemical masks the number of fluorine atoms contained in the substance (*i.e.*, Polyfluoro—N,N—bis(2—hydroxyethyl) hexanamide). In this case, the generic name would include chemical substances containing anywhere from 2 to 11 fluorine atoms, at any combination of positions in hexanamide portion of the chemical substance. Again, such a generic chemical name would literally include hundreds or thousands of distinct chemical substances. Studies have clearly indicated that the extent of halogenation of a chemical (i.e., the degree to which hydrogen atoms bound to carbon atoms have been replaced with halogen atoms) dramatically impacts its toxicity and environmental and biological fate. *See*, e.g., *id.* It is absolutely pertinent to know the extent to which it is halogenated in order to understand the potential risk of a chemical substance.

The generic names EPA's guidance allows to be substituted for specific chemical identities are far from capable of narrowing, to any manageable number, the universe of compounds to which a health and safety study relates, nor do they foster an understanding of the underlying chemistry that determines a chemical's toxicity.

B. Examples of Actual Generic Names Chemical Manufacturers have Provided When Submitting "Substantial Risk" Notices to EPA under TSCA Section 8(e) and PMNs

Even with the existence of EPA guidance on the generation of generic chemical names, chemical companies have often chosen generic names that diverge completely from that guidance. For example, in the most recent monthly batch of Section 8(e) substantial risk notices received by the agency (January 2012) there are:

- four notices for chemicals whose identities have been masked and instead identified as "Confidential *2,"
- four notices for chemicals whose identities have been masked and instead identified as "Substance A *2,"
- four notices for chemicals whose identities have been masked and instead identified as "Substance B *2," and
- a notice for a chemical merely identified by the generic name "hydrofluorocarbon."[19]

These substantial risk notices could refer to any of a virtually infinite number of chemicals.

The same derisory approach to selection of generic names by chemical companies occurs in the context of PMN notifications. The most recent posting of PMNs received by EPA in the Federal Register (February 22, 2012) includes chemicals with specific identities that have been masked and replaced instead with generic names such as "Acrylic copolymer" and "Aromatic diazo compound."[20] While these PMN notifications are not notifications of health and safety studies (see next section), the selection of generic names, wholly at odds with EPA's 1985 guidance, is frequent and ongoing in PMN submissions as well as in section 8(e) notices.

C. Example of a Generic Name of a Chemical for Which a PMN was Filed in the Past that Included Health and Safety Studies

In recent months, pursuant to its 2010 policies, EPA has begun declassifying health and safety studies and disclosing the associated specific chemical identities. *See* EPA, Increasing Transparency in TSCA, http://www.epa.gov/oppt/existingchemicals/pubs/transparency.html (last visited Feb. 29, 2012). Some of these health and safety studies were submitted with PMNs filed in the past. We have examined a number of these. For example:

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[19] EPA, 8(e) and FYI Submissions Received January 2012, http://www.epa.gov/oppt/tsca8e/pubs/8emonthlyreports/2012/8ejan2012.html (last visited Feb. 29, 2012).

[20] Certain New Chemicals; Receipt and Status Information, 77 Fed.Reg. 35, 10512-10515 (Feb. 22, 2012), http://www.gpo.gov/fdsys/pkg/FR-2012-02-22/pdf/2012-4069.pdf

- A PMN filed in 1999, for which a Notice of Commencement of manufacture was filed in 2002, was originally identified in the PMN merely as a "Halogenated Alkane." EPA recently posted a declassified copy of this PMN, which discloses the specific chemical identity as Propane, 1,1,1,3,3-pentachloro-.[21] Relative to the examples provided earlier, this generic name is more consistent with the 1985 guidance.

- Attached to the PMN were a Material Safety Data Sheet (MSDS) and a number of health and safety studies. These documents reveal the chemical to have considerable toxicity. The MSDS states, among other warnings:

    - POSSIBLE REPRODUCTIVE HAZARD May cause birth defects or other reproductive harm based on animal data.
    - INHALATION - TOXIC. Exposure to high concentrations of vapor or mist can cause central nervous system depression with symptoms of headache, dizziness, stupor, loss of consciousness or death, depending on concentration and duration of exposure. Overexposure to vapors has been associated with severe adverse effects on the liver, kidney, and nasal epithelium. Exposure to high concentrations of similar materials can cause irregular heartbeat, cardiac arrest and death.
    - CHRONIC EFFECTS - Studies in laboratory animals indicate that exposure to vapors of this material can cause adverse effects on the liver, kidney, and nasal epithelium. Overexposure to similar materials has been shown to cause adverse effects on the fetus, such as birth defects.[22]

Until EPA's recent declassification,[23] none of these disturbing effects could have been linked to this chemical – not by any member of the public, workers handling this chemical, health or environmental researchers or other professionals, state, Tribal or local government officials, or companies using or contemplating using this chemical. None of these stakeholders would have been able to search for this information even had they somehow known the specific chemical identity, because only the generic name had been disclosed. All they would have known would be that some mystery "Halogenated Alkane" now on the market had these toxic properties.

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[21] A copy of the original PMN, declassified chemical identity and associated health and safety studies is *available at* http://java.epa.gov/oppt_chemical_search/download?filename=09022526800b411d_P-99-1327_10-12-2011_PMN_PHCS_Original - 51990001327.pdf.

[22] *See id.*

[23] Unfortunately, EPA inadvertently kept the specific chemical identity of this "halogenated alkane" confidential well past the time of its receipt of the NOC in 2002, in which the submitter relinquished its CBI claim on chemical identity that it had made in its PMN submission. Nevertheless, even had EPA promptly disclosed this chemical's identity at the time of the NOC filing, three years would have passed during which abundant, critical toxicity data for the chemical would have been kept secret from key public, governmental, and market constituencies mentioned above.

ACC's proposed approach would allow the indefinite masking of the specific identity of such a chemical and its replacement by a useless generic name that could refer to any of hundreds or thousands of chemicals.

V. Even Under TSCA Section 14(a), Chemical Identity is Not Shielded from Disclosure Unless it is CBI

Pursuant to TSCA Section 14, even outside of the context of health and safety studies, chemical identity is not shielded from disclosure unless it qualifies as a trade secret under the Freedom of Information Act (FOIA), 5 U.S.C. § 552(b)(4). EPA regulations implementing the requirements of FOIA set forth the substantive criteria to be applied in making confidentiality determinations, which include, among other things, that "the information is not, and has not been, reasonably obtainable without the business's consent by other persons (other than governmental bodies) by use of legitimate means . . ." and either "the business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business's competitive position" or the information is voluntarily submitted to the government and disclosure would likely impair the government's ability to obtain necessary information in the future. 40 C.F.R. § 2.208(c), (e)(1)-(2). Although the release of trade secrets is associated with some costs, changes in technology and, particularly, the ability of competitors to "deformulate" or reverse engineer the ingredients of products has an impact on whether chemical identity is in fact reasonably obtainable and, also, whether disclosure is likely to cause competitive harm. *See Kewanee Oil Co. v. Bicron Corp*., 416 U.S. 470, 476 (1974) ("[T]rade secret law . . . does not offer protection against discovery by fair and honest means, such as by independent invention, accidental disclosure, or by so-called reverse engineering . . . ."); *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 93 F. Supp. 2d 1, 10-11 (D.D.C. 2000) ("No competitive harm can result if the information is publicly available through other sources.").[24] Any cost-benefit analysis of EPA's proposal should take into account that, even in the absence of the provisions of TSCA Section 14(b), chemical identity may not be considered CBI given increasing transparency worldwide as well as advances in the technology available to reverse engineer chemicals.

Worthington Compressors, Inc. v. Costle, 662 F.2d 45 (D.C. Cir.1981), sets forth the *cost* considerations in assessing whether reverse engineering makes information publicly available and hence not protected from disclosure. In *Worthington*, a manufacturer of air compressors requested all production verification and quality control reports submitted by other air compressor manufacturers. *Id.* at 48. The district court granted summary judgment for the EPA, which had disclosed the requested information. *Id.* at 52-53. The district court reasoned that the requested information was public because noise level information could be ascertained

[24] The party requesting the information "bears the initial burden of producing evidence to show that the information is available through public sources, but the burden of persuasion remains with the party opposing disclosure." *Id.* (citing *NW Coal. for Alts. to Pesticides v. Browner,* 941 F.Supp. 197, 202 (D.D.C.1996)).

through private testing (by purchasing a compressor and duplicating standard noise test procedures) and design and engineering specifications could be reverse engineered. *Id.* The D.C. Circuit reversed, finding that summary judgment was precluded, but recognized that the ability to reverse engineer raised factual questions about whether information was publicly available:

> In this case, . . . the requested information is available, at some cost, from an additional source. In our view, this requires that the inquiry be expanded to include two considerations: (1) the commercial value of the requested information, and (2) the cost of acquiring the information through other means.
>
> The first consideration is based on the obvious fact that a submitter can suffer competitive harm only if the requested information has commercial value to competitors. When the information does have commercial value, the second consideration comes into play. If the information is freely or cheaply available from other sources, such as reverse engineering, it can hardly be called confidential and agency disclosure is unlikely to cause competitive harm to the submitter.

Id. at 51. Because material factual issues existed as to the cost of seeking the requested information, the commercial value of such information, and the practicality of reverse engineering, the D.C. Circuit found that summary judgment was inappropriate.

In *NW Coalition for Alternatives to Pesticides v. Browner*, plaintiffs sought the common names and CAS numbers of inert ingredients in certain pesticides. 941 F. Supp. 197 (D.D.C. 1996). The court determined that the common names and CAS numbers of the ingredients were not trade secrets, but nevertheless found that some of the information was protected as CBI. *See id.* at 202-205. The court noted that:

> There is no genuine issue of material fact as to the economic feasibility of identifying the common names and CAS numbers of inert ingredients through 'reverse engineering.' Plaintiffs state that reverse engineering to identify *ingredients* is common practice in the pesticide industry. . . . Defendants state that it is costly and impracticable to reverse engineer pesticide *formulas*. Neither factual proposition is challenged, and both are accepted as true. Lying between those two propositions, however, and unexplained on this record, is the question of how difficult and costly it is or would be to learn the identity of the inert ingredients of the six pesticides in question by reverse engineering.

Id. at 202. The court found that EPA failed to meet its "burden of both production and persuasion" on this point. *Id.*

VI. Disclosure is Associated with Social and Economic Benefits, Which Were Ignored by ACC

ACC quotes a Council on Environmental Quality report to show that chemical identities in health and safety studies have recognized economic value. Specifically, ACC points to language in the report stating that "specific identification of a product in a health and safety study may inform competitors that a product has commercial value or that it is used in a particular manufacturing process," and that "although the sensitivity of releasing confidential data is greatest at the beginning of a product's commercial life cycle, release of such data about an existing product may have the same economic consequences as disclosure of confidential data regarding a new product." ACC White Paper at 5; *see also* U.S. Council on Environmental Quality, Toxic Substances Strategy Committee, Toxic Chemicals and Public Protection: A Report to the President 48 (1980). ACC, however, fails to mention that these statements are selectively taken from the first half of a section in the CEQ report that first assesses the drawbacks of routine disclosure of confidential health and safety data, and then goes on to consider the benefits of routine disclosure. *See* CEQ Toxic Substances Strategy Committee, Toxic Chemicals and Public Protection at 49-54. The report points out, "the need for assessing risks from the increasing number of potentially toxic chemicals in the environment and the well-recognized right of citizens to be informed about their health and well-being are strong arguments for public access to data reflecting on the safety or health effects of a chemical to which they may be exposed." *See id.* at 49. The report further notes the following consequences of nondisclosure:

> First, the value of scientific peer review is lost, and errors in test methods or data may not be detected. Failure to identify potential dangers because of faulty data may have serious health or environmental consequences. Second, the possibility of needless duplication of tests, with the attendant waste of scarce scientific resources, is enhanced. Third, advancement of scientific knowledge can be hindered by one researcher's lack of access to the experience and insights of another.

Id. at 50. The CEQ report concluded that not all health and safety data was confidential, and that "the trend in recent legislation, particularly TSCA and FIFRA, is to accord confidential health, safety, and efficacy data less protection from disclosure than general confidential information on the ground that the public has an especially strong interest in access to these data." *Id.* at 47.

Undoubtedly, there are costs associated with disclosure of previously confidential chemical identities. Yet, when information is withheld from the public and the scientific community, there are also adverse consequences. The empirical relationship between confidentiality of business information on the one hand and innovation and economic growth

on the other, assumed by ACC, is inconclusive.[25] For example, confidentiality can hamper productive innovation in a way that may offset any innovation incentive provided by the prospect of maintaining trade secrets. When an inventor maintains a trade secret, innovators will not be able to learn from the scientific and technological insights that led to the original invention, slowing the overall rate of innovation.[26] To make matters worse, under trade secret laws, firms are likely to waste scarce resources pursuing an invention that has already been made rather than investing in socially productive innovation.[27]

The lack of publicly available information also impedes the market from responding to the demand for safer chemicals because sufficient information is not available to help the market, generally, and consumers, in particular, distinguish safe from unsafe chemicals. Secrecy has an impact on all players in the market: consumers, workers, downstream industrial users of chemicals, and others. As the Final Report of California's Green Chemistry Initiative stated, "There are tens of thousands of chemicals in use today, but we know very little about how they effect people or the environment. This information gap prevents the free market from working properly to stimulate the innovation of safer, healthier substitutions." California Green Chemistry Initiative, Final Report at 1 (December, 2008); *see also* Joseph H. Guth, et al., *Require Comprehensive Safety Data for All Chemicals*, 17 New Solutions 233, 234 (2007) (data gaps "constitute a `failure' in the chemicals market economy that prevents buyers of chemicals from choosing safer alternatives and reduces market incentives for the chemical industry to innovate safer chemicals").

[25] *See* U.S. Council on Environmental Quality, Toxic Substances Strategy Committee, Toxic Chemicals and Public Protection: A Report to the President 47 (1980) ("it is unclear today how much that incentive [to innovate] is affected by disclosure of confidential health, safety, and efficacy data").
[26] Robert G. Bone, *A New Look at Trade Secret Law: Doctrine in Search of Justification*, 86 Cal. L. Rev. 241, 266-267 (1998).
[27] *Id.*; *see also* Thomas O. McGarity and Sidney A. Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 Harv. L. Rev., 837, 845 (1980).

We appreciate your consideration.

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On behalf of the Signatory Organizations

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National Medical Association
Science Environmental Health Network
Women's Voices for the Earth

cc. Lee Anderson, BlueGreen Alliance
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Janet Nudelman, Breast Cancer Fund
Jeanne Rizzo, Breast Cancer Fund
Jamie Silberberger, Women's Voices for the Earth
Erin Switalski, Women's Voices for the Earth

McPartland
Attachment C

Smart Innovation

THE OPPORTUNITY FOR SAFER PRESERVATIVES

EDF
ENVIRONMENTAL DEFENSE FUND™
Finding the ways that work

Addendum 196

ABOUT ENVIRONMENTAL DEFENSE FUND

The goal of the health program at Environmental Defense Fund (EDF) is to improve human and ecological health through reductions in exposure to harmful chemicals and pollution. EDF's health program uses the dual levers of public policy and corporate leadership to phase harmful substances and practices out of the market and introduce safer products and practices into mainstream use. We encourage and support innovations that work toward this end.

ABOUT THIS REPORT

The Preservative Innovation Project (PIP) offers a framework to direct innovation for specific functional classes of chemicals (e.g., preservatives) in order to drive safer chemicals and products into the marketplace. The primary output of the framework is a uniformly-developed, baseline set of toxicological information for a representative set of chemicals in a functional class. Such baseline toxicological information can be used to inform design criteria for new chemical research and development (R&D); provide a basis of toxicological comparison for new chemicals entering the market; and direct additional chemical testing and research where data are lacking or insufficient. The PIP was led by Environmental Defense Fund, with input from several companies including Active Micro Technologies, Beautycounter, Clariant, and Seventh Generation as well as the Green Chemistry and Commerce Council. However, EDF is the sole author of this report. Organizations that provided input into its development should not be interpreted as endorsers of the content.

This report describes the PIP framework, and the findings and conclusions drawn from the toxicological evaluation of a subset of commercially available preservatives.

ACKNOWLEDGEMENTS

EDF would like to thank ToxServices **(www.toxservices.com)** for its contribution to this report, including conducting GreenScreen® for Safer Chemicals assessments, providing project management support, and helping compile this report.

Contents

Executive Summary

More and more consumers, commercial purchasers, and retailers are seeking products that are responsibly and sustainably produced (Headwaters, 2016), and as part of this movement, are increasingly attentive to the potential health and environmental hazards of product ingredients. Recent reports show that the health impacts of products are a number one priority for consumers (Headwaters, 2016; UL, 2013). Finding ways to innovate safer ingredients and products is proving to be good for consumers and the environment, and for business growth. By using safer chemicals in products, retailers and manufacturers stay ahead of regulatory developments, better manage brand and financial risk, and demonstrate that they are responsive to consumer demand.

Some of the most important chemicals in consumer products today are preservatives. Preservatives play an important role in preventing microbial growth in products such as personal care products. However, certain preservatives have come under regulatory and market pressure for human health and environmental concerns (see Appendix A). Given these realities and the ubiquity of preservatives in products, the development of safer, effective preservatives is crucial and offers a prime opportunity for innovation.

Did you know?

of consumers worldwide are **willing to pay more** for sustainable products.

of consumers globally say "uses no harsh chemicals or toxins" is a major driver when buying beauty and personal care products.

Many major retailers, including Walmart and Target, are creating or expanding upon chemical policies that ban or limit the use of toxic chemicals in the products they sell.

The lack of comprehensive, structured, transparent, and comparable toxicological information across different functional classes (e.g., preservatives) is a major obstacle to safer chemical innovation. Such baseline information is invaluable for setting safer chemical design criteria that chemical and product developers can use in their efforts to design or select safer chemicals.

EDF launched the Preservative Innovation Project (PIP) in 2015 to show the utility of generating baseline sets of toxicological information to guide chemical innovation efforts.

Focusing on preservatives used in personal care products, EDF assembled a small group of leading preservative suppliers and product manufacturers (PIP working group) to identify a set of 16 commercially available preservatives (PIP preservatives) on which to conduct a toxicological evaluation. Specifically, PIP preservatives were evaluated using the GreenScreen® for Safer Chemicals Method (GreenScreen®) — a comprehensive chemical hazard assessment method that has been used by government, public interest groups, researchers, and businesses alike to evaluate and characterize the potential hazards of chemicals.

Meaningful baseline toxicological information should be the following:

COMPREHENSIVE

An extensive set of human and ecological toxicity endpoints are evaluated.

STRUCTURED

Data collection, assessment, and integration is accomplished in a consistent manner for all chemicals evaluated. Hazard characterizations are assigned according to pre-specified criteria.

TRANSPARENT

The approach used to research hazard characterizations including how data are identified, collected, and integrated is clear, documented, and made available. Similarly, full chemical hazard assessments are made available.

COMPARABLE

Hazard characterizations across all endpoints are presented in a consistent, accessible manner that allows for easy comparison.

GreenScreen® for Safer Chemicals Method

In the GreenScreen® method, a licensed GreenScreen® assessor evaluates chemicals across 18 human health, environmental, and physical hazard endpoints and assigns a hazard score for each endpoint using prescribed criteria.

An indication of the degree of confidence in the assignment of a hazards score, based on the quality of the available data, is also provided. Where data are insufficient to assign a hazard score, the assessor will assign the endpoint as a Data Gap.

Finally, an overall toxicity 'Benchmark' score that integrates hazard scores and data gaps across all 18 endpoints is determined using a specified algorithm (CPA, 2011).

CPA, 2011, 2012a, 2013 *See Appendix C for a fuller description of GreenScreen®*

GreenScreen® is strictly a hazard assessment method, developed to rigorously evaluate the intrinsic hazard of chemicals. GreenScreen® does not assess how much exposure there may be to a given chemical, an important aspect in the evaluation of the overall risk a chemical may present to an individual or ecosystem. Often product manufacturers will manage chemical risk by limiting the amount of a chemical in a product, in other words, by managing the extent of exposure to the chemical. However, identification and use of ingredients with lower intrinsic hazard is an important and effective way to reduce overall potential health concerns. Individuals are often exposed to mixtures of chemicals presenting similar hazards, and certain subpopulations can be more susceptible than others to these exposures. Innovation efforts focused on creating inherently safer chemicals complement important restrictions on the amount of chemicals presenting hazard permitted in products—together reducing overall impacts to human health and the environment.

Key Findings

GreenScreen® evaluations of the 16 PIP preservatives yielded the following key findings:

- Several PIP preservatives scored Moderate to Very High for skin sensitization, skin irritation, eye irritation, and acute and chronic aquatic toxicity.
- Only one PIP preservative, DMDM hydantoin, received a High hazard score for a GreenScreen® Group I human health endpoint. Specifically, DMDM hydantoin scored High for carcinogenicity, as a result of its release of formaldehyde, a known human carcinogen. GreenScreen® Group I human health endpoints represent hazards that lead to chronic or life-threatening health effects that may result from low dose exposures and include carcinogenicity, mutagenicity, reproductive toxicity, developmental toxicity, and endocrine activity (see Appendix C).
- Confidence in the assignment of hazard scores varied widely across the PIP preservatives. For any given preservative, endpoints assigned scores with high confidence ranged from two (caprylohydroxamic acid, Lactobacillus ferment, sorbitan caprylate) to 14 (methylisothiazolinone and piroctone olamine), with an average of ten endpoints assigned scores with high confidence.
- All PIP preservatives had data gaps for at least two hazard endpoints. The number of data gaps ranged from two (IPBC, methylisothiazolinone, propylparaben, and sorbic acid) to 13 (Lactobacillus ferment), and the average number of data gaps across the preservatives was four.
- Data gaps were consistently encountered in the assessment of endocrine activity, neurotoxicity, and respiratory sensitization.

Endpoints often scored as Moderate to Very High

PIP PRESERVATIVE	HAZARD ENDPOINT			
	Skin sensitization	Skin irritation	Eye irritation	Acute and/or chronic aquatic toxicity
Benzyl alcohol	●		●	
Caprylohydroxamic acid			●	●
Caprylyl glycol			●	●
DMDM Hydantoin	●	●		●
EDTA		●	●	●
Ethylhexylglycerin	●		●	●
Gluconolactone				
IPBC	●		●	●
Lactobacillus ferment				
Methylisothiazolinone	●	●	●	●
Phenoxyethanol			●	
Piroctone olamine		●	●	●
Propylparaben	●	●		●
Sorbic acid	●	●	●	●
Sorbitan caprylate				●
Undecylenic acid	●	●	●	●
TOTAL	**8**	**7**	**11**	**12**

Overall GreenScreen® Benchmark (BM) scores for the PIP preservatives were as follows:

BENCHMARK 4	Safer chemical	• None
BENCHMARK 3	Use but still opportunity for improvement	• Caprylyl glycol • Sorbitan caprylate
BENCHMARK 3DG	[Data gaps exist] Use but still opportunity for improvement[1]	• Gluconolactone
BENCHMARK 2	Use but search for safer alternatives	• Benzyl alcohol • EDTA • Ethylhexylglycerin • IPBC • Methylisothiazolinone • Phenoxyethanol • Piroctone olamine • Propylparaben • Sorbic acid • Undecylenic acid
BENCHMARK 1	Avoid - Chemical of high concern	• DMDM Hydantoin
BENCHMARK U	Unspecified due to insufficient data	• Caprylohydroxamic acid • Lactobacillus ferment

1 A Benchmark score of 3DG means that the chemical meets the hazard classification requirements of a Benchmark 4 but does not meet the data gap requirements; however, it does meet the data gap requirements for a Benchmark 3

The EDF Preservative Innovation Project was successful in identifying human and ecological hazard hotspots among the preservatives evaluated, such as skin sensitization and aquatic toxicity as well as identifying endpoints for which data were frequently lacking or insufficient, such as endocrine activity and neurotoxicity. The baseline information generated through the PIP can be used to set design criteria and define data needs for safer preservative R&D, as well as provide a basis of toxicological comparison for new preservatives entering the market.

One element not pursued in the PIP was a measure of performance—that is how well a particular chemistry provides the function of interest, in this case product preservation. Performance is key to evaluate when comparing safer alternative options. For example, a product manufacturer typically needs to prevent the growth of a broad spectrum of pathogenic microorganisms including certain bacteria, yeast, and molds. Because preservatives can be effective against some microorganisms and not others, a product manufacturer needs to consider preservative performance or efficacy alongside potential toxicity. Indeed, product manufacturers often use blends of preservative chemicals in their products to achieve broad spectrum preservation. Similarly, alternative preservative chemicals may be effective against the same microorganism but under different formulation conditions or at different concentrations, which in turn can impact product cost and toxicological risk. EDF was ultimately unable to pursue performance testing of the PIP preservatives due to funding and time constraints.

Full GreenScreen® reports are available **online.**

Recommendations

MAKE HAZARD A PRIORITY INNOVATION CRITERION.

Certain preservatives are under increased scrutiny by regulators, consumers, and the marketplace due to concerns around impacts to human health or the environment. Though safety is considered in the development of new chemicals, it is not often touted as the major benefit or driving force of innovation. EDF maintains that the development of inherently safer chemicals should be recognized as just as significant and innovative as the development of chemicals with improved performance. Innovation efforts focused on creating inherently safer chemicals complement important restrictions on the amount of potentially hazardous chemicals permitted in products—together reducing overall impacts to human health and the environment.

TACKLE HAZARD HOTSPOTS.

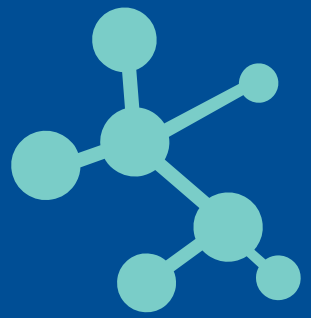
Preservative innovation efforts should focus on tackling identified hazard hotspots (i.e., endpoints that received the highest hazard scores in this assessment): skin sensitization, skin irritation, eye irritation, acute aquatic toxicity, and chronic aquatic toxicity.

AVOID TRADING OFF HAZARDS.

While certain hazard endpoints were not identified as hazard hotspots for the preservatives evaluated in the PIP, as a general practice, chemical innovators should continue to consider all potential hazards in the development of new preservatives. This is to avoid the introduction of a new hazard while tackling another.

Did you know?

The inherent hazard of a chemical is a critical component in evaluating its relative safety. The reduction of hazard is a defining element in the Twelve Principles of Green Chemistry and leading alternatives assessment methodologies.



FOR MORE INFORMATION SEE:

- National Academy of Sciences - A Framework to Guide Selection of Chemical Alternatives
- BizNGO - The Commons Principles for Alternatives Assessment
- Interstate Chemicals Clearinghouse - Alternatives Assessment Guide, Version 1.1
- U.S. Environmental Protection Agency - Design for the Environment (DfE) Alternatives Assessments

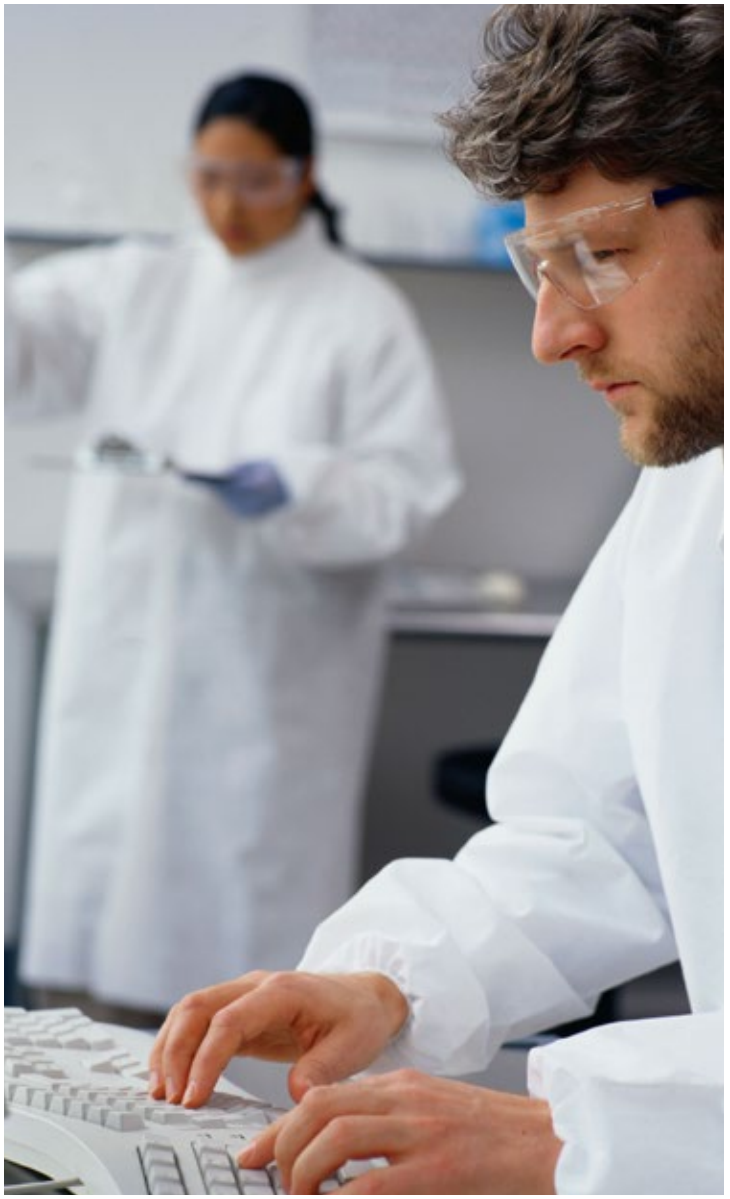
Recommendations

CREATE A CHEMICALS ASSESSMENT CLEARINGHOUSE.

EDF calls for the creation of an independent chemicals assessment clearinghouse that would provide comprehensive, structured, transparent, and comparable health and safety assessments of chemicals in a centralized, web-accessible repository. Operational standards would be established for qualifying assessors to develop and contribute assessments to the clearinghouse, ensuring quality assurance, and updating assessments to reflect the most current science—all with an eye toward producing assessments that are meaningful, actionable, and credible to actors along the supply chain. Such a clearinghouse would serve as a significant resource to various stakeholders looking to move the dial on safer chemistry, whether as a chemical innovator looking for information to inform design criteria or to show how a new chemistry represents an improvement over the status quo; as a product manufacturer searching for safer product formulation and fabrication options; or as a retailer interested in understanding what alternatives may be available for chemicals they are looking to move away from. Assessments from the clearinghouse would also indicate where toxicity data are lacking or insufficient, and thus where more chemical testing is needed. Finally, an independent chemical assessment clearinghouse holds the potential for participating parties to share the cost burden of producing objective, mutually desired and beneficial toxicological assessments of chemicals.

In sum, the framework employed in the EDF PIP provides valuable baseline toxicological information for preservative innovation, and can be similarly applied to other chemical functional classes.

Additional evaluation lenses, for example performance, could be included in future similar efforts so long as these evaluations are also conducted in a consistent and transparent manner. Ultimately an independent chemical assessment clearinghouse is needed to replicate the work of the PIP at scale across multiple chemical functional classes.



Introduction

Recent reports show that the health impacts of products are a high priority for consumers (Headwaters, 2016; UL, 2013). At the same time market research shows increasing market growth opportunities in safer chemistry (ASBC, 2015). Finding ways to innovate safer chemicals and products is proving to be good for consumers and the environment, and for business growth. By using safer chemicals in products, retailers and manufacturers can get ahead of regulatory developments, better manage brand and financial risk, and demonstrate that they are responsive to consumer demand.

One major obstacle facing chemical innovation is the lack of widely-available baseline sets of toxicological information across different chemical functional classes that are comprehensive, structured, transparent, and comparable. Such baseline toxicological information can be used to develop data-driven criteria or benchmarks for safer chemical design, or selection, during chemical and product R&D respectively.

Meaningful baseline toxicological information should be the following:

- ✓ COMPREHENSIVE
- ✓ STRUCTURED
- ✓ TRANSPARENT
- ✓ COMPARABLE

“Although the investment in safer chemistry is nascent and difficult to quantify, there are signs that it is growing. The rise in patents for more sustainable chemistry based on a search of US Patent and Trademark Office records shows increasing momentum and evolving industry capacity. Interest by investors of various types in advanced materials and technological innovation further underscores how capital could flow toward safer chemistry in the future.”

(ASBC, 2015, pg. 9)

CHECK OUT THESE CASE STUDIES of leading companies that have found opportunity in safer chemistry:

- AkzoNobel
- Seventh Generation
- Panera Bread

In 2015, EDF launched the Preservative Innovation Project (PIP) to pilot a framework to address this need. The core steps of the framework are:

- Identify a chemical functional class (e.g., preservatives) and corresponding use scenario (e.g., personal care products) for which innovation is desired owing to human health or ecological concerns
- Conduct chemical hazard assessments (e.g., GreenScreen® for Safer Chemicals method) on a representative subset of chemicals in the identified chemical functional class

The results of chemical hazard assessments provide:

- Input into the development of design criteria for safer chemical innovation through the identification of hazard hotspots
- A basis of toxicological comparison for evaluating new chemicals entering the market
- Information that innovators and product manufacturers can use to demonstrate how a particular innovation is an improvement over existing options with regard to toxicity
- Identification of hazard data gaps for which additional information or testing is needed in order to provide a more complete picture of potential toxicity concerns

Importantly, the EDF PIP did not attempt to tackle every aspect of what is involved in taking chemical innovations to market including performance testing, examination of production scalability, and cost. These are all important considerations in chemical innovation beyond the scope of this particular effort.

WHY A FOCUS ON PRESERVATIVES?

EDF chose to focus on preservatives in personal care products given consumer, marketplace, and regulatory pressures on certain commonly used preservatives (see Appendix A). As a functional class, preservatives present an interesting innovation challenge. Personal care products can become contaminated through contaminated raw materials, poor manufacturing conditions, inadequate packaging, or consumer use. Product preservation is important for protecting consumers from pathogenic microorganisms that can cause skin infections, eye infections, and in the most severe cases, illness or death (Brannan, 1997). Since some degree of biocidal activity is required for preservative efficacy, many preservatives on the market today typically carry some degree of inherent hazard.

Did you know?

A preservative is a chemical agent that may be added to food, cosmetics, pharmaceuticals, and other products to prevent the growth of microorganisms or slow down or prevent decomposition through oxidation.

Preservatives extend the shelf life of products.

Preservatives can be synthetic, like parabens, or naturally occurring, like salt.

In the 1960s and early 1970s, cosmetic contamination with certain microorganisms was a large problem. Cases of skin infections, rashes, eye infections, and even blindness resulted from use of contaminated cosmetics.

Chemical preservatives are widely used in cosmetics to prevent the growth of microorganisms, like bacteria and fungi, some of which are pathogenic and can be hazardous to human health.

Manufacturers are faced with the challenge of identifying preservative systems that sufficiently protect consumers against pathogenic microbial contamination while minimizing any potential hazards of the preservatives themselves.

EDF believes that dedicated innovation effort on preservatives will yield new, promising chemical or other solutions that achieve product preservation with far less human health and ecological hazard concerns than those of certain preservatives currently in use in the market today.

Additionally, a number of public-private initiatives have emerged to advance preservative innovation including the UC Berkeley Greener Solutions project and the Green Chemistry and Commerce Council (GC3) Preservative Project (UC Berkeley, 2016; GC3, 2016). The UC Berkeley Greener Solutions project involved a student-led literature search of naturally-occurring compounds with antimicrobial properties, in collaboration with Beautycounter and Seventh Generation; while the GC3 project is pursuing a **crowdsourcing challenge** to surface promising safe and effective preservation options and involves several businesses and a handful of state and environmental groups.

These efforts focus primarily on identifying new preservation solutions, while the EDF PIP focused on providing baseline information that can be used to:

1. inform safer preservative design criteria, and
2. serve as a basis against which to evaluate new preservatives options with regard to hazard.

We hope that the work conducted through the PIP will serve as a resource in solution-seeking preservative innovation efforts.

EDF CONVENED A GROUP OF ORGANIZATIONS TO PROVIDE INPUT INTO THE PIP, INCLUDING:

- ACTIVE MICRO TECHNOLOGIES
- BEAUTYCOUNTER
- CLARIANT
- GREEN CHEMISTRY AND COMMERCE COUNCIL
- SEVENTH GENERATION
- TOXSERVICES

These organizations represent businesses in the personal care product arena that either use or supply preservatives; experts skilled in chemical assessment; or individuals with expertise in public-private collaborations focused on green chemistry. However, EDF is the sole author of the PIP report and fully responsible for the final content.

Selection of PIP Preservatives

EDF conducted a market scan of preservatives used in personal care products, followed by consultation with and consensus by the PIP Working Group to select preservatives to evaluate in the PIP.

EDF's market scan included an online examination of preservatives used in over 40 personal care product brands. In particular, EDF looked at skin lotion products since these products are applied directly to the body, intended for prolonged exposure, and require the use of preservatives to prevent microbial contamination (Poulsen and Strandesen, 2011; Kabara and Orth, 1996).

Preservatives used in skin lotions were identified using two approaches: 1) reading online product ingredient lists for chemicals explicitly identified as preservatives, and 2) cross-referencing lotion product ingredient lists against chemicals classified as preservatives by various cosmetic ingredient resources, including the Cosmetic Ingredient Review (CIR) compendium (CIR, 2014a), Preservatives for Cosmetics, 3rd edition, by David Steinberg (Steinberg, 2012), and chemical supplier data sheets. While the compiled candidate list was extensive, it was not exhaustive; there are a large number of personal care product brands and not all brands post product ingredient information online.

The PIP working group then reviewed the candidate list of preservatives using criteria for inclusion developed by the group. Chemicals were excluded or proposed by the group, and through a consensus process a final set of 16 preservatives were identified for evaluation (see Table 1). Additional information on each preservative can be found in Appendix B.

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Through a consensus process a final set of 16 preservatives were identified for evaluation.

Table 1: Preservatives selected for PIP

PRESERVATIVE	Microbial Activity
Benzyl alcohol 100-51-6	Most active against gram-positive bacteria, moderately active against gram-negative bacteria and yeast/mold (Siegert, 2014)
Caprylohydroxamic acid [2] 7377-03-9	Most active against mold; also active against gram-positive and negative bacteria and yeast (Hase et al., 1971; Ammendola et al., 2009; Bravo and Lazo, 1993; Steinberg, 2012).
Caprylyl glycol 1117-86-8	Active against gram-positive and gram-negative bacteria; moderate activity for yeasts/molds (Dr. Straetmans, 2008); also able to improve the effectiveness of other preservatives at concentrations lower than their typical use level.
DMDM Hydantoin 6440-58-0	Good activity for gram-positive and gram-negative bacteria; moderately active against yeasts and molds (Siegert, 2014).
Ethylenediaminietetraacetic Acid (EDTA) 60-00-4	Reduces availability of iron for microbial growth; not active against gram-positive bacteria; enhances activities of antibacterial agents particularly against drug-resistant gram-negative microbes by increasing the permeability of cellular membranes; prevents growth of yeast and molds in zinc-dependent fashion (Brul et al., 1997; CIR, 2002).
Ethylhexylglycerin 70445-33-9	Most active against gram positive bacteria; boosts the efficacy of traditional preservatives and acts as an antimicrobial stabilizer (Steinberg, 2012; Leschke and Siegert, 2008).
Gluconolactone 90-80-2	The active agent, gluconic acid, is able to control microbial growth by reducing pH to a level that inhibits putrefactive and toxigenic bacteria growth (Lemay et al., 2000).
Iodopropynyl Butylcarbamate (IPBC) 55406-53-6	Very active against yeast and mold, inadequate activity against bacteria (Steinberg, 2012).
Lactobacillus ferment 1686112-36-6	Active against gram-positive and gram-negative bacteria; moderate activity for yeasts and molds (Active Micro, 2014).
Methylisothiazolinone (MIT) 2682-20-4	Good to moderate activity for gram-positive and gram-negative bacteria, yeasts, and molds (Siegert, 2014).
Phenoxyethanol 122-99-6	Most active against gram-negative bacteria; moderate activity for gram-positive bacteria and yeasts/molds (Siegert, 2014).
Piroctone olamine 68890-66-4	Good activity against gram-positive bacteria, yeasts and molds; moderate activity for gram-negative bacteria (Clariant, 2004; Siegert, 2014).
Propylparaben 94-13-3	Good activity against gram-positive bacteria, yeasts and molds; moderate activity against gram-negative bacteria (Seigert, 2014).
Sorbic acid 110-44-1	Most active against yeast and mold and poorly active against bacteria (CIR, 2012).
Sorbitan caprylate [2] 60177-36-8	Demonstrates efficacy against gram-positive bacteria; not active against gram-negative bacteria and undetermined for yeasts/molds (Clariant, 2012; Wagh et al., 2012).
Undecylenic acid 112-38-9	Active against fungi (Spectrum, 2015a); no activity against bacteria (Siegert, 2014).

2 The vast majority of the PIP preservatives are considered traditional preservative compounds; however, caprylohydroxamic acid and sorbitan caprylate, which may be considered non-traditional preservatives or preservative boosters, were also selected for this project because of their increased use in consumer products and a recommendation for inclusion by the PIP working group

Hazard Assessment Method

EDF selected the GreenScreen® for Safer Chemicals (GreenScreen®) method for the hazard evaluation of the PIP preservatives (CPA, 2011; CPA, 2012a; CPA, 2013). The GreenScreen® method was chosen as the preferred method because of its structured, comprehensive design; the thorough documentation of data considered and results; and its record of application by both public and private sector entities. EDF contracted with ToxServices, an environmental consultancy with extensive experience performing chemical hazard and risk assessments, to perform the hazard evaluations. ToxServices is a highly experienced, licensed user of GreenScreen® tools.

WHY GREENSCREEN® IS USEFUL TO COMPANIES

Consumer product companies are under pressure to to develop products with less toxic chemicals. Many have programs which ban or restrict the use of highly toxic chemicals in the products that they manufacture or sell. They use tools like GreenScreen® to help meet these increasing demands. GreenScreen® can be used to evaluate current product formulations to identify problematic chemicals and help select safer alternatives to those chemicals. GreenScreen® can also be used during product development to select less toxic chemicals from the start of product design, avoiding chemical substitutions down the road, which can be costly and time consuming. A growing number of professionals in companies like GOJO Industries and Hewlett Packard have become Authorized GreenScreen® Practitioners.

GreenScreen® for Safer Chemicals

The GreenScreen® for Safer Chemicals is a comparative hazard assessment method designed to evaluate substances across a broad set of human and environmental toxicity endpoints. The method has been used by companies, advocacy groups, and state chemicals regulatory programs. It is also recognized as a hazard assessment platform for several standards and ecolabels, including the U.S. Green Building Council's LEED certification and the Cradle to Cradle Certified Product Standard™ and material health certificate.

The GreenScreen® method is publically available and includes evaluation of 18 human health, environmental, and physical hazard endpoints.

Groupings of GreenScreen Hazard Endpoints

Human Heath Group I	**Human Heath Group II**	**Human Heath Group II***	**Environmental Toxicity & Fate[3]**	**Physical Hazards**
Carcinogenicity	Acute Mammalian Toxicity	Systemic Toxicity & Organ Effects (repeated dose)	Acute Aquatic Toxicity	Reactivity
Mutagenicity & Genotoxicity	Systemic Toxicity & Organ Effects (single dose)	Neurotoxicty (repeated dose)	Chronic Aquatic Toxicity	Flammability
Reproductive Toxicity	Neurotoxicity (single dose)	Skin Sensitization	Persistence	
Developmental Toxicity including Neurodevelopmental Toxicity	Skin Irritation	Respiratory Sensitization	Bioaccumulation	
Endocrine Activity	Eye Irritation		Other Ecotoxicity studies when available	

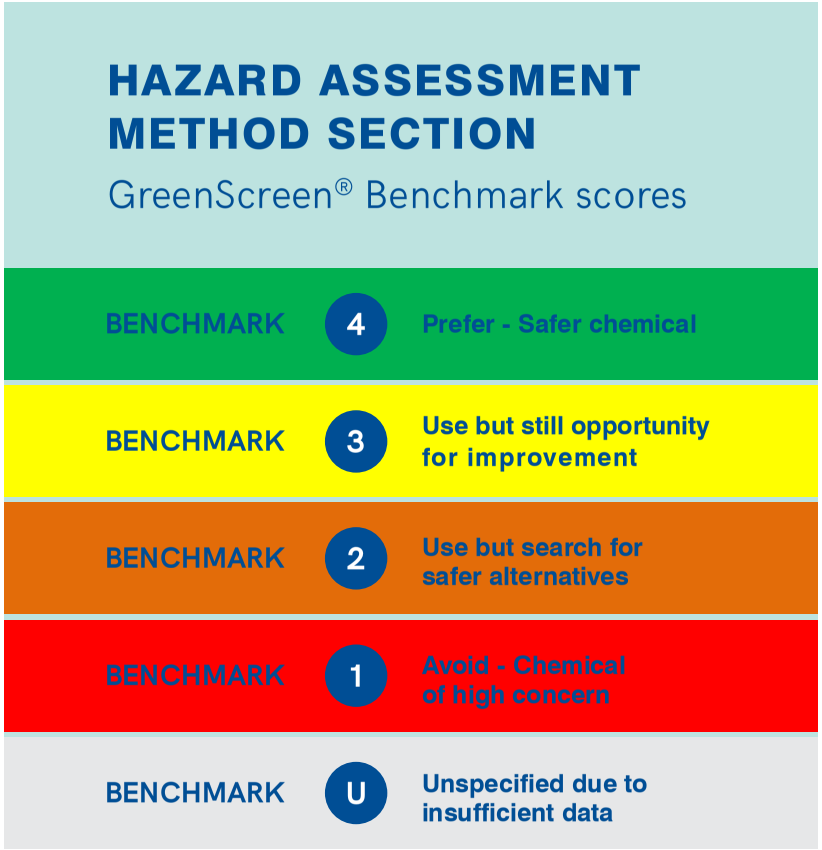
Evaluation of a chemical across each of the hazard endpoints includes a review of specified authoritative lists,[3] primary studies, and other available data. A hazard score—Very Low, Low, Moderate, High, or Very High—is assigned to each endpoint along with a confidence level (low or high) to indicate the quality and robustness of the dataset used to assign the hazard score. If insufficient or no data exist for a particular endpoint, Data Gap is assigned as the score. Finally, an overall GreenScreen® Benchmark™ score is assigned, ranging from 1 ("Avoid-Chemical of High Concern") to 4 ("Prefer-Safer Chemical"). A fuller description of the GreenScreen® for Safer Chemicals method can be found in Appendix C.

GreenScreen® List Translator

The GreenScreen® List Translator is an abbreviated version of the full GreenScreen® method that involves screening chemicals against specified authoritative lists and not a review of primary studies (CPA, 2012b).

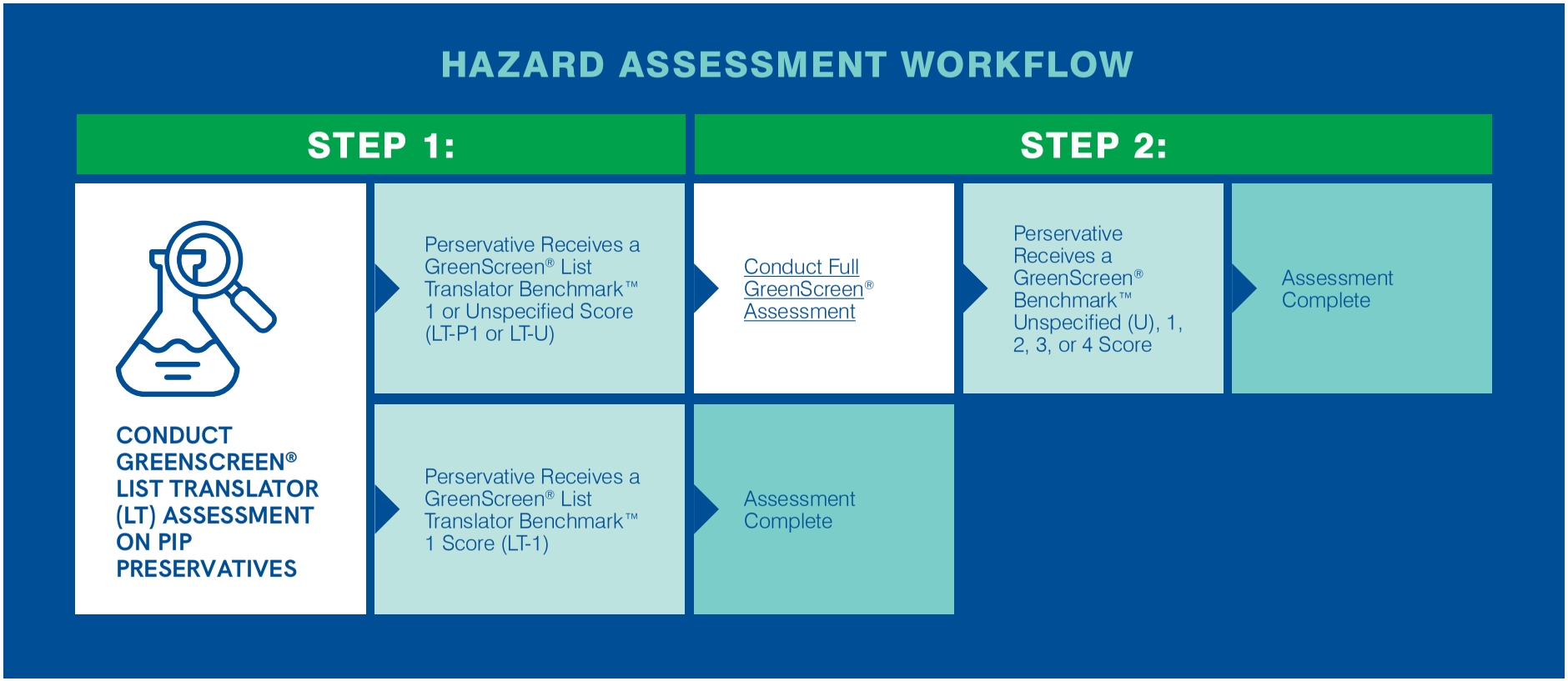
The List Translator approach involves a review of specified authoritative lists to identify chemicals that can be classified as LT-1, which is equivalent to a GreenScreen® Benchmark 1 ("Avoid-Chemical of High Concern"), or an LT-P1, which may be equivalent to a Benchmark 1 following a further review of data. LT-1 chemicals have been identified by authoritative bodies as carcinogens, mutagens, reproductive or developmental toxicants, endocrine active compounds, or persistent, bioaccumulative, and toxic (PBT) compounds. An LT-U score means that there is insufficient information from the screening of authoritative lists alone to assign a Benchmark LT-1 or LT-P1 score, and a full GreenScreen® must be performed to assign a Benchmark score. Additional information on GreenScreen® List Translator can be found **here.**

3 GreenScreen® specified authoritative lists can be found at http://www.greenscreenchemicals.org/



Hazard Assessment Workflow

EDF and ToxServices used the following two-step hazard screening and assessment approach for the PIP:



STEP 1

GreenScreen® List Translator Screening

For the GreenScreen® List Translator screening, ToxServices used the Pharos Chemical and Materials Library online tool that automates the GreenScreen® authoritative list search and benchmark equivalency scoring (Pharos, 2015). As none of the selected preservatives were identified as LT-1 chemicals, each proceeded to the full GreenScreen® hazard assessment.

STEP 2

GreenScreen® for Safer Chemicals Assessment

ToxServices performed a full GreenScreen® hazard assessment on all PIP preservatives (**available online here**). In addition to the review of specified GreenScreen® authoritative lists, ToxServices evaluated existing, publically available data that at a minimum included a search of the data sources listed to the right.

ToxServices also requested that PIP working group members provide any data not available in the public domain to facilitate as comprehensive of hazard assessments as possible. ToxServices offered participants the opportunity to share such data under a non-disclosure agreement (NDA). One supplier provided additional data to ToxServices and granted explicit permission to include the data in the GreenScreen® assessments included in the current report.

DATA RESOURCES

COSMETIC INGREDIENT REVIEW (CIR)

CIR Compendium

EUROPEAN CHEMICALS AGENCY (ECHA)

International Uniform Chemical Information Database (IUCLID)

Information on Chemicals

HUMAN AND ENVIRONMENTAL RISK ASSESSMENT (HERA)

HERA on ingredients of household cleaning products

WORLD HEALTH ORGANIZATION (WHO)

International Agency for Research on Cancer (IARC)

OTHER

ToxPlanet

EU Scientific Committee on Consumer Safety (SCCS) Opinions

INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY (IPCS)

INCHEM

NATIONAL INSTITUTES OF HEALTH (NIH)

ChemIDplus

Hazardous Substances Data Bank (HSD)

National Toxicology Program (NTP)

Toxline

NATURAL MEDICINES

Database of natural medicines

ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD)

OECD Existing Chemicals Database

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY (US EPA)

High Production Volume Information System (HPVIS)

In the absence of sufficient data and where possible, ToxServices identified and evaluated a structurally similar chemical or class of chemicals for which data were available. ToxServices toxicologists identified appropriate structural analogs using the resources listed below.

Analogs were selected according to guidance in the U.S. Environmental Protection Agency's procedure for identifying analogs (USEPA, 2010), ECHA's read across assessment framework (ECHA, 2015), and OECD's guidance on grouping of chemicals (OECD, 2014).

In cases where suitable analogs could not be identified, ToxServices used modeling software to assess hazards as appropriate for a given preservative and the domain of the model.

Once all data were collected, a hazard score (i.e., high or low) and accompanying confidence level in that score (i.e., high confidence in bold, reduced confidence in italics) was assigned for each of the 18 GreenScreen® hazard endpoints according to the method. In instances where no data were available, no suitable analogs were identified, and modeling was not possible, a data gap (DG) was assigned for that hazard endpoint.

ToxServices also performed a GreenScreen® List Translator evaluation on known transformation products of PIP preservatives, such as biodegradation or hydrolysis products that are likely to occur across the chemical's lifecycle, and are likely to persist and be encountered in the environment (CPA, 2013). Considering the Benchmark score of the parent compound and transformation products, a final Benchmark™ score was assigned to the evaluated preservative, applying the more conservatwive of the two scores.

RESOURCES TO IDENTIFY STRUCTURAL ANALOGS

NIH

ChemIDplus structural similarity search

OECD

OECD Toolbox

U.S. EPA

Analog Identification Methodology (AIM)

Chemical Assessment Clustering Engine (ChemACE)

MODELING SOFTWARE RESOURCES

ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD)

ChemIDplus structural similarity search

TOXTREE

Toxic Hazard Estimation by Decision Tree Approach

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY (USEPA)

Ecological Structure Activity Relationships (ECOSAR) Predictive Modeling

EPI (Estimation Program Interface) Suite™

OncoLogic™ - A computer system to evaluate the carcinogenic potential of chemicals

VEGA

Vega Predictive model for skin sensitization

Results of GreenScreen® for Safer Chemical Assessments

The results of the GreenScreen® List Translator[4] and full GreenScreen® hazard assessments are presented below in Table 2 and on page 23, in Table 3.

TABLE 2

GREENSCREEN® LIST TRANSLATOR RESULTS FOR PIP CHEMICALS

LIST TRANSLATOR SCORE	*Chemicals*	
LT-U	• Benzyl alcohol • Caprylohydroxamic acid • DMDM Hydantoin • Ethylhexylglycerin • Gluconolactone	• Lactobacillus ferment • Phenoxyethanol • Sorbic acid • Sorbitan caprylate • Undecylenic acid
LT-P1	• Caprylyl glycol • EDTA • IPBC	• Methylisothiazolinone • Piroctone olamine • Propylparaben

4 Definitions and explanations of the List Translator scores can be found in the GreenScreen® List Translator subsection of the Hazard Assessment Method section

TABLE 3 GreenScreen® Hazard Assessments

CHEMICAL NAME & CAS#	Group I Human Health					Group II and II* Human Health									Ecotox		Fate		Physical		
	Carcinogenicity	Mutagenicity	Reproductive Toxicity	Developmental Toxicity	Endocrine Activity	Acute Toxicity	Systemic Toxicity		Neurotoxicity		Skin Sensitization*	Respiratory Sensitization*	Skin Irritation	Eye Irritation	Acute Aquatic Toxicity	Chronic Aquatic Toxicity	Persistence	Bioaccumulation	Reactivity	Flammability	
							s	r*	s	r*											
Benzyl alcohol 100-51-6	L	L	L	*M*	DG	**M**	DG	L	*M*	*H*	**H**	DG	L	**H**	L	L	vL	vL	*L*	L	2
Caprylohydroxamic acid 7377-03-9	DG	*L*	DG	*L*	DG	*L*	DG	*M*	DG	DG	*L*	DG	L	*H*	*H*	*H*	vL	*vL*	*L*	*L*	U
Caprylyl glycol 1117-86-8	*L*	L	*L*	L	DG	L	DG	L	**M**	L	L	DG	L	**H**	*H*	*M*	vL	vL	*L*	L	3
DMDM Hydantoin 6440-58-0	*H*	**M**	L	L	DG	L	*M*	L	DG	DG	**M**	*M*	*M*	L	**H**	**M**	vL	vL	*L*	L	1
EDTA 60-00-4	L	L	L	**M**	DG	*L*	*M*	**H**	DG	DG	L	DG	*M*	**H**	**H**	**H**	*M*	vL	*L*	L	2
Ethylhexylglycerin 70445-33-9	*L*	*L*	*M*	*L*	DG	**M**	**M**	*M*	DG	*L*	*M*	DG	L	**vH**	**M**	**M**	*M*	vL	*L*	L	2
Gluconolactone 90-80-2	*L*	*L*	*L*	L	DG	L	L	L	DG	DG	*L*	DG	*L*	*L*	L	*L*	vL	*vL*	*L*	L	3_{DG}
IPBC 55406-53-6	L	L	*M*	*M*	*M*	**H**	DG	**H**	*M*	*L*	**H**	DG	L	**vH**	**vH**	**vH**	L	vL	L	*L*	2
Lactobacillus ferment 1686112-36-6	DG	DG	DG	DG	DG	DG	DG	DG	DG	DG	L	DG	L	*L*	*L*	DG	*vL*	DG	*L*	*L*	U
Methylisothiazolinone 2682-20-4	*L*	L	L	L	DG	**vH**	**M**	*M*	**M**	DG	**H**	*L*	**vH**	**vH**	**vH**	**vH**	L	vL	*L*	L	2
Phenoxyethanol 122-99-6	L	L	*L*	**M**	DG	**M**	DG	*L*	**M**	L	L	DG	L	**H**	L	*L*	vL	vL	*L*	L	2
Piroctone olamine 68890-66-4	*L*	L	L	*M*	DG	L	**M**	L	**M**	DG	L	DG	**H**	**vH**	**vH**	**H**	*vL*	L	L	L	2
Propylparaben 94-13-3	*L*	L	L	*L*	*M*	L	L	L	DG	L	**M**	DG	*M*	L	**H**	**H**	vL	vL	*L*	L	2
Sorbic acid 110-44-1	L	L	L	*M*	*M*	L	*M*	L	DG	L	**M**	DG	*H*	**H**	**M**	**M**	vL	vL	*L*	L	2
Sorbitan caprylate 60177-36-8	*L*	*L*	*L*	*L*	DG	*L*	*L*	*L*	DG	*L*	*L*	DG	*L*	*L*	*M*	*M*	*vL*	vL	*L*	L	3
Undecylenic acid 112-38-9	*L*	L	*L*	L	DG	*L*	L	L	DG	DG	*M*	DG	*H*	**H**	**vH**	*vH*	*vL*	*L*	*L*	L	2

KEY:

- **vL** = Very Low
- **L** = Low
- **M** = Moderate
- **H** = High
- **vH** = Very High
- *italics* indicates hazard scores assigned with low confidence
- **bold** indicates hazard scores assigned with high confidence
- **s** indicates single exposure
- **r** indicates repeated exposure
- * indicates Group II health hazards evaluated based on repeated exposures to a chemical

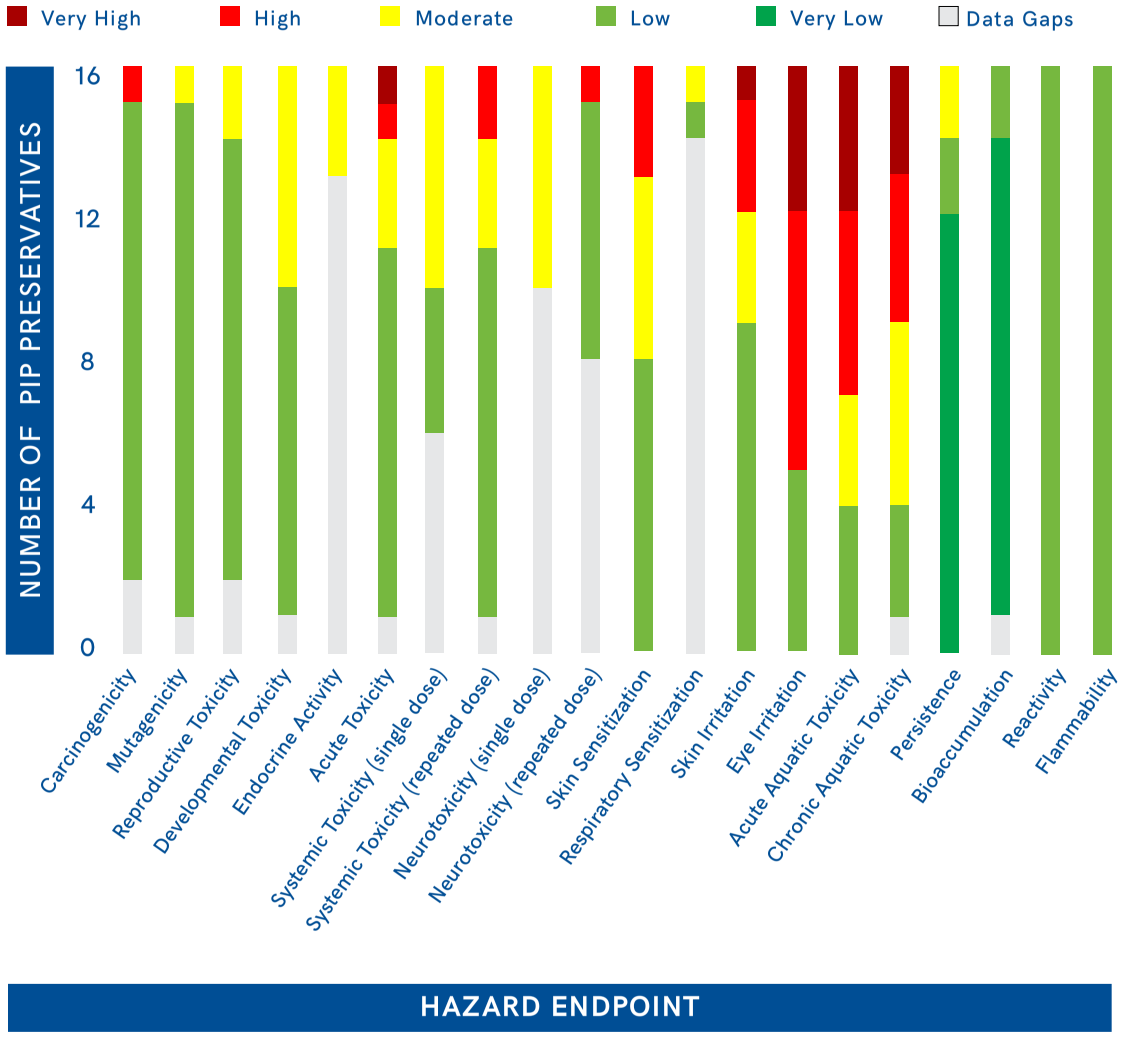
Discussion of Results

A review of the GreenScreen® chemical hazard assessments reveals certain trends across the hazard profiles of the PIP preservatives including shared hazard endpoints of concern, a lack of toxicity across other hazard endpoints, and hazard endpoints for which toxicity could not be assessed due to a consistent lack of data. Full GreenScreen® assessments of PIP preservatives are **provided online**.

While the assessments developed in this project provide valuable, baseline data for preservative innovators, it is important to acknowledge that a larger review of additional preservatives could reveal new trends or refine those discussed below. Similarly, toxicological analyses of PIP preservatives were limited to publically available data which varied in quality and breadth across chemicals and endpoints. That the EDF PIP identified certain hazard hotspots among the PIP preservatives, as discussed below, does not mean that other endpoints should be ignored during new preservative research and development. Innovators should continuously assess the full scope of potential toxicity of their solutions.

PIP PRESERVATIVE HAZARD SCORES BY HAZARD ENDPOINT

The stacked bar chart depicts the number of PIP preservatives assigned to distinct GreenScreen® hazard scores (Very Low, Low, Moderate, High, Very High, or Data Gap) within each hazard endpoint.



Hazard Trends

SKIN SENSITIZATION

Skin sensitization concerns were identified for eight of the 16 preservatives evaluated: five preservatives received a Moderate hazard score based on low to moderate potency and/or frequency of occurrence of sensitization responses, and three received a High hazard score for skin sensitization based on high potency and/or frequency of occurrence. Most (six of eight) of these Moderate and High hazard scores were assigned with high confidence as the hazard classifications were based on experimental data in laboratory animals, patch tests in humans, and human case reports that support a skin sensitization effect.

Skin sensitization is of particular relevance for ingredients in personal care products like lotions where normal use of the product results in prolonged and repeated contact with skin. Such use conditions provide increased opportunity for induction of sensitization to occur. Because an individual, once sensitized, is typically sensitized for life, he or she will be susceptible to allergic responses upon all subsequent exposures.

These results indicate that skin sensitization is a priority area for innovation. Preservative innovation efforts should focus on developing preservatives with lower skin sensitization potential, and broadening the palette of available preservatives to minimize repeated and high aggregate exposures to individual or classes of skin sensitizing chemicals that may lead to cross-sensitization reactions.

SKIN AND EYE IRRITATION

Nearly half (seven of 16) of the preservatives were found to be skin irritants and the majority (11 of 16) were found to be eye irritants. Of the skin irritants, three received a score of Moderate, three received a score of High, and one received a score of Very High. Of the eye irritants, seven received a score of High and four received a score of Very High.

A score of Very High for skin or eye irritation means that the undiluted preservative can irreversibly damage the skin or eyes. Although individuals are unlikely to be exposed to undiluted preservatives through use of consumer products, skin and eye irritation remain important areas for preservative innovation given the extent and degree of irritation identified, and in consideration of potential occupational exposures.

SKIN ALLERGIES

Skin sensitization is of particular relevance for ingredients in personal care products like lotion where normal use of the product results in prolonged and repeated contact with skin.

Hazard Trends

TOXICITY TO AQUATIC ORGANISMS AND ENVIRONMENTAL FATE

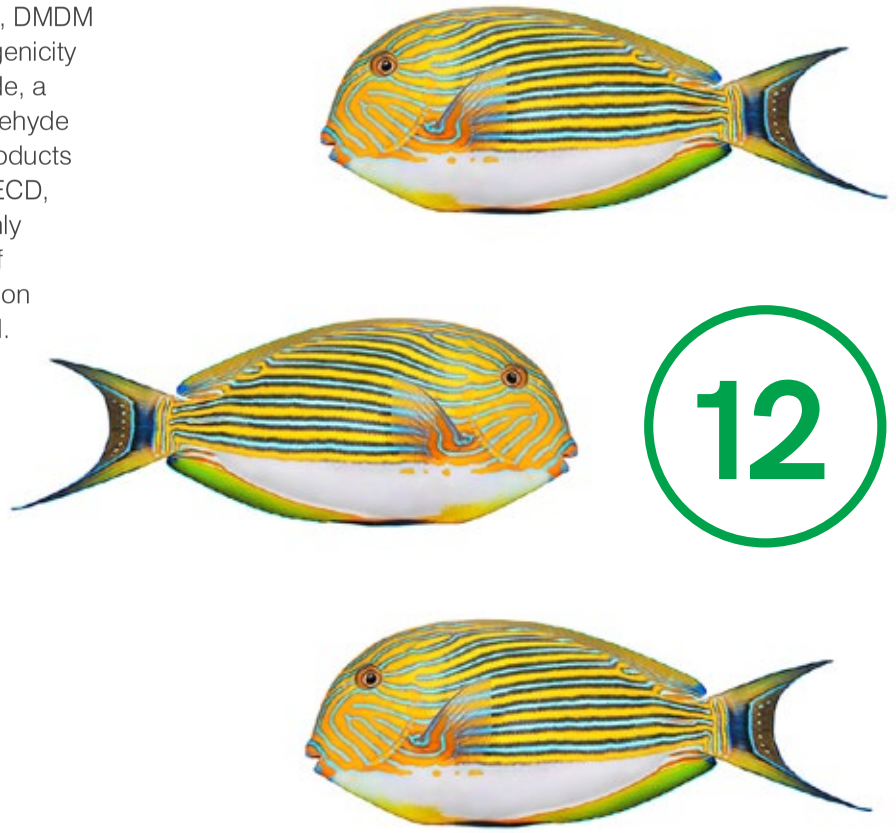
Toxicity to aquatic organisms was a frequent hazard across the PIP preservatives. Of the 16 preservatives evaluated, 12 received scores of Moderate or above for acute aquatic toxicity, with nine receiving scores of High or Very High. These same 12 preservatives also received scores of Moderate or above for chronic aquatic toxicity, with seven receiving scores of High or Very High. Additionally, two of these 12 preservatives were shown or predicted to be Moderately persistent with the remainder expected to be readily or rapidly biodegradable (i.e., not persistent). None of the preservatives are expected to be bioaccumulative based on experimental data, physicochemical properties, and/or modeled data.

While the Low scores for persistence and bioaccumulation may help to limit ecological impacts, the development of preservatives with lower intrinsic hazards to aquatic organisms is an area for innovation given the widespread use of these compounds and their potential for direct release into the environment (Northcott et al., 2013; Santos et al., 2016; Zhang et al., 2015; Bledzak et al., 2014).

CARCINOGENICITY AND MUTAGENICITY

The GreenScreen® hazard assessments did not indicate any trends for carcinogenicity or mutagenicity. Only one preservative, DMDM hydantoin, scored High for carcinogenicity based on its release of formaldehyde, a known human carcinogen. Formaldehyde release, via hydrolysis, occurs in products and may also occur in the body (OECD, 2016). DMDM hydantoin was the only chemical that displayed evidence of genotoxicity sufficient for classification following the GreenScreen® method.

Of the 16 preservatives evaluated, 12 received scores of Moderate or above for acute aquatic toxicity, with nine receiving scores of High or Very High.



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Hazard Trends

REPRODUCTIVE AND DEVELOPMENTAL TOXICITY

Most of the preservatives did not show evidence of reproductive toxicity (12 of 14) or developmental toxicity (nine of 14) sufficient for classification based on the data available and following the GreenScreen® method. Due to a lack of data, caprylohydroxamic acid and Lactobacillus ferment, could not be evaluated for reproductive toxicity; further, Lactobacillus ferment could not be evaluated for developmental toxicity.

Seven preservatives showed evidence of reproductive toxicity and/or developmental toxicity and received Moderate toxicity scores for those endpoints. Both moderate scores for reproductive toxicity and four of six Moderate scores for developmental toxicity were reported with reduced confidence as they are based on equivocal or mixed results, effects of uncertain toxicological significance, or poorly reported studies.

In sum, based on the available data, the 16 preservatives examined did not indicate reproductive or developmental toxicity as priority focus areas for targeted innovation. It is important to note however that reproductive and developmental toxicity are complex endpoints and that traditional guideline studies—which represent the vast majority of the available studies for the PIP—have been critiqued with regard to their ability to sufficiently capture reproductive and developmental effects, particularly as they relate to endocrine disruption (Vandenberg, 2014; Endocrine Society, 2015).

ACUTE AND SYSTEMIC TOXICITY

The GreenScreen® hazard assessments did not reveal any specific trends for acute toxicity or systemic toxicity but did identify some preservatives with hazards for these endpoints.

Of the preservatives with acute toxicity data available (15 of 16), three received a score of Moderate, one received a score of High, and one received a score of Very High.

Although six of 10 preservatives with single dose systemic toxicity data available received scores of Moderate, per the GreenScreen® method these scores were assigned based on evidence of respiratory tract irritation, which is a localized effect rather than a true systemic effect. The remainder of chemicals with available data for single dose systemic toxicity were all assigned a score of Low. Repeated dose systemic toxicity data were available for 15 of the 16 preservatives. The majority, 10 of 15, received a score of Low for this endpoint, while three of 15 received a score of Moderate and two of 15 received a score of High. A review of the data for chemicals that received toxicity scores of Moderate or High for repeated dose systemic toxicity did not reveal any specific trends regarding shared target organs/systems.

Hazard Endpoints Often Scored as Data Gaps

Data gaps were frequently encountered for certain hazard endpoints, including endocrine activity, respiratory sensitization, and neurotoxicity.

ENDOCRINE ACTIVITY

Only three out of 16 of the preservatives assessed in this report had data adequate to assess and assign hazard scores for endocrine activity: IPBC, propylparaben, and sorbic acid. All three of these preservatives received Moderate hazard scores for endocrine activity and these scores were assigned with low confidence.

The lack of available endocrine activity data is not a unique challenge to preservatives. Few endocrine activity-explicit endpoints are evaluated in guideline toxicology studies typically used by industry, and which represent the majority of the available data for the PIP (also see reproductive and developmental toxicity above). There are some in vitro and in vivo assays designed to include an evaluation of endocrine activity and disruption, such as those incorporated into U.S. EPA's Endocrine Disruption Screening Program (USEPA, 2017a; USEPA, 2017b), but they are not routinely conducted, and while useful do not yet comprehensively examine effects on the endocrine system.

New predictive toxicity testing approaches continue to be developed and have the potential to provide more information for the evaluation of endocrine activity. Strengthening and employing these new methods should be a focal point of chemical innovation efforts broadly.

RESPIRATORY SENSITIZATION

The majority of the preservatives (14 of 16) were assigned a Data Gap for respiratory sensitization. For the two preservatives assigned scores—methylisothiazolinone, Low and DMDM hydantoin, Moderate—both scores were assigned with low confidence. The scarcity of data for this endpoint in part stems from the lack of agreed upon in vitro or animal models for the testing of respiratory sensitization in guideline studies.

Typically, respiratory sensitizers are identified through case reports, especially in occupationally exposed individuals. Historically, chemicals are presumed to be a low hazard for respiratory sensitization if there is a lack of case reports over a long history of use. However, this is a very limited approach and further, such a history of use is not likely available for more recently developed preservatives. Consideration of respiratory sensitization becomes extremely important for those exposed occupationally and for consumers if there is inhalation potential.

As approaches for assessing respiratory sensitization continue to be developed and refined, a more in depth assessment of the respiratory sensitization potential of preservatives should be pursued.

Data gaps were frequently encountered for certain hazard endpoints, including endocrine activity, respiratory sensitization, and neurotoxicity.

NEUROTOXICITY

The evaluated preservatives are not well studied with regard to their potential for neurotoxicity (i.e., adverse changes to the structure and/or function of the nervous system). GreenScreen® separately evaluates neurotoxicity data from studies that administer single doses or repeated doses. Of the 16 PIP preservatives, six chemicals were evaluated in single-dose studies and eight chemicals were evaluated in repeated-dose studies.

In the single-dose studies, which evaluated the neurological effects of a single, high dose of each chemical preservative, all six chemicals produced reversible neurological effects. These six chemicals, therefore, received a GreenScreen® score of Moderate for neurotoxicity. In studies evaluating neurological effects of repeated doses of chemical preservatives, only one chemical, benzyl alcohol, received a GreenScreen® score of High, as it was shown to produce irreversible neurotoxicity in humans. However, these effects were observed in infants exposed intravenously and therefore the relevance to oral, dermal, and inhalation exposures expected through use as a preservative in a personal care product is uncertain. The other seven preservatives with repeated dose toxicity data were scored as Low hazard.

Insufficient data were available to assess potential single- or repeated- dose neurotoxicity of six preservatives (i.e. chemicals had data gaps for single- and repeated-dose studies), highlighting the need for data development such as predictive toxicity testing approaches, targeted histopathological evaluations of the brain, functional observational batteries, and specialized behavioral tests.

Variability in Data Gaps and Confidence Assigned to Hazard Scores

A review across all of the GreenScreen® hazard assessments reveals variability in both the quantity and quality of available data for evaluating individual preservatives. This variability is manifest by differences in the number of hazard endpoint scores assigned as Data Gaps, and the extent to which hazard endpoint scores were assigned with low or high confidence.

For any given preservative, the number of hazard endpoint scores assigned as Data Gaps ranged from two (IPBC, methylisothiazolinone, propylparaben, and sorbic acid) to 13 (Lactobacillus ferment). The average number of Data Gap scores across all preservatives was four.

There was also a large range in the number of hazard endpoint scores assigned with high confidence for any given preservative. In accordance with the GreenScreen® method, endpoints were assigned a toxicity score with high confidence when relatively complete datasets were available for that endpoint (e.g., measured data was available on the actual preservative under consideration and not a surrogate). Other endpoints were assigned a toxicity score with low confidence because they relied on weak surrogates, modeled data, studies of limited reliability due to methodological and/or reporting deficiencies, or studies producing mixed results. For any given preservative, endpoints assigned scores with high confidence ranged from two (capyrylohydroxamic acid, Lactobacillus ferment, sorbitan caprylate) to 14 (methylisothiazolinone and piroctone olamine). All of the evaluated preservatives had at least three hazard endpoint scores assigned with low confidence.

Hazard Analysis Summary

The GreenScreen® chemical hazard assessments provided a consistent evaluation of the human health and environmental toxicity and fate of 16 preservatives currently in use in personal care products. Key findings include:

- Several PIP preservatives scored Moderate to Very High for skin sensitization, skin irritation, eye irritation, and acute and chronic aquatic toxicity (see table to the right).
- Only one PIP preservative, DMDM hydantoin, received a High hazard score for a GreenScreen® Group I human health endpoint. Specifically, DMDM hydantoin scored High for carcinogenicity, as a result of its release of formaldehyde, a known human carcinogen. GreenScreen® Group I human health endpoints represent hazards that lead to chronic or life-threatening health effects that may result from low dose exposures and include carcinogenicity, mutagenicity, reproductive toxicity, developmental toxicity, and endocrine activity (see Appendix C).
- Confidence in the assignment of hazard scores varied widely across the PIP preservatives. For any given preservative, endpoints assigned scores with high confidence ranged from two (capyrylohydroxamic acid, Lactobacillus ferment, sorbitan caprylate) to 14 (methylisothiazolinone and piroctone olamine), with an average of ten endpoints assigned scores with high confidence.

Endpoints often scored as Moderate to Very High

	HAZARD ENDPOINT			
PIP PRESERVATIVE	**Skin sensitization**	**Skin irritation**	**Eye irritation**	**Acute and/ or chronic aquatic toxicity**
Benzyl alcohol	●		●	
Capyrylohydroxamic acid			●	●
Caprylyl glycol			●	●
DMDM Hydantoin	●	●		●
EDTA		●	●	●
Ethylhexylglycerin	●		●	●
Gluconolactone				
IPBC	●		●	●
Lactobacillus ferment				
Methylisothiazolinone	●	●	●	●
Phenoxyethanol			●	
Piroctone olamine		●	●	●
Propylparaben	●	●		●
Sorbic acid	●	●	●	●
Sorbitan caprylate				●
Undecylenic acid	●	●	●	●
TOTAL	**8**	**7**	**11**	**12**

- All PIP preservatives had data gaps for at least two hazard endpoints. The number of data gaps ranged from two (IPBC, methylisothiazolinone, propylparaben, and sorbic acid) to 13 (Lactobacillus ferment), and the average number of data gaps across the preservatives was four.
- Data gaps were consistently encountered in the assessment of endocrine activity, neurotoxicity, and respiratory sensitization.
- Overall GreenScreen® Benchmark (BM) scores across the PIP preservatives were as follows:

BENCHMARK 4 Safer chemical	• None
BENCHMARK 3 Use but still opportunity for improvement	• Caprylyl glycol • Sorbitan caprylate
BENCHMARK 3DG [Data gaps exist] Use but still opportunity for improvement*	• Gluconolactone
BENCHMARK 2 Use but search for safer alternatives	• Benzyl alcohol • EDTA • Ethylhexylglycerin • IPBC • Methylisothiazolinone • Phenoxyethanol • Piroctone olamine • Propylparaben • Sorbic acid • Undecylenic acid
BENCHMARK 1 Avoid - Chemical of high concern	• DMDM Hydantoin
BENCHMARK U Unspecified due to insufficient data	• Caprylohydroxamic acid • Lactobacillus ferment

* A Benchmark score of 3DG means that the chemical meets the hazard classification requirements of a Benchmark 4 but does not meet the data gap requirements; however, it does meet the data gap requirements for a Benchmark 3

Conclusion and Recommendations

With the PIP, EDF and its collaborators set out to provide a resource for chemical innovators and product manufacturers looking to create or discover new, safer chemical options for product preservation.

Specifically, the PIP sought to develop comprehensive toxicological profiles for a representative set of commercially available preservatives in a structured, transparent, and comparable manner using the GreenScreen® for Safer Chemicals method.

Based on the results of the PIP, EDF recommends the following for those pursuing preservative innovation:

MAKE HAZARD A PRIORITY INNOVATION CRITERION.

Certain preservatives are under increased scrutiny by regulators, consumers, and the marketplace due to concerns around impacts to human health or the environment. Though safety is considered in the development of new chemicals, it is not often touted as the major benefit or driving force of innovation. EDF maintains that the development of inherently safer chemicals should be recognized as just as significant and innovative as the development of chemicals with improved performance. Innovation efforts focused on creating inherently safer chemicals complement important restrictions on the amount of potentially hazardous chemicals permitted in products—together reducing overall impacts to human health and the environment.

TACKLE HAZARD HOTSPOTS.

Preservative innovation efforts should focus on tackling identified hazard hotspots (i.e., endpoints that received the highest hazard scores in this assessment): skin sensitization, skin irritation, eye irritation, acute aquatic toxicity, and chronic aquatic toxicity.

AVOID TRADING OFF HAZARDS.

While certain hazard endpoints were not identified as hazard hotspots for the preservatives evaluated in the PIP, as a general practice, chemical innovators should continue to consider all potential hazards in the development of new preservatives. This is to avoid the introduction of a new hazard while tackling another.

CREATE A CHEMICALS ASSESSMENT CLEARINGHOUSE.

EDF calls for the creation of an independent chemicals assessment clearinghouse that would provide comprehensive, structured, transparent, and comparable health and safety assessments of chemicals in a centralized, web-accessible repository. Operational standards would be established for qualifying assessors to develop and contribute assessments to the clearinghouse, ensuring quality assurance, and updating assessments to reflect the most current science—all with an eye toward producing assessments that are meaningful, actionable, and credible to actors along the supply chain. Such a clearinghouse would serve as a significant resource to various stakeholders looking to move the dial on safer chemistry, whether as a chemical innovator looking for information to inform design criteria or to show how a new chemistry represents an improvement over the status quo; as a product manufacturer searching for safer product formulation and fabrication options; or as a retailer interested in understanding what alternatives may be available for chemicals they are looking to move away from. Assessments from the clearinghouse would also indicate where toxicity data are lacking or insufficient, and thus where more chemical testing is needed. Finally, an independent chemical assessment clearinghouse holds the potential for participating parties to share the cost burden of producing objective, mutually desired and beneficial toxicological assessments of chemicals.

Market demand for safer chemicals is significant and growing. Interests center on driving harmful chemicals out of commerce and ushering in safer solutions that, together, work to protect public health and the environment.

From a business perspective, investments in safer chemicals means getting ahead of regulatory demands, expanding market potential, and mitigating against future business risk, such as market deselection of a chemical of concern and legal fines imposed from the mismanagement of hazardous waste.

Innovators play a crucial role in developing safer solutions -- from using less toxic chemicals to making engineering changes that reduce or eliminate the need for a chemical of concern. Access to data-driven, uniformly-developed toxicological profiles of the sort developed in the PIP is invaluable for defining robust criteria to push safer chemical R&D.

Ideally, the PIP framework could be replicated across other functional classes of chemicals and product types. However, replication of the PIP framework is contingent, among other things, on the availability of robust data for chemical assessments. Greater public access to chemical health and safety information enables comprehensive assessments of chemicals, strengthening the type of evaluation undertaken in the PIP, and identification of true data gaps that would benefit from additional research.

EDF calls for the creation of an independent chemicals assessment clearinghouse to replicate the PIP framework at scale for multiple chemical functional classes. Such a clearinghouse would provide a significant resource to those looking to move the dial on safer chemistry by facilitating credible, data-driven decision-making that moves us all toward a more sustainable, healthy world.

APPENDIX A

Preservative Regulatory and Market Action Landscape

Regulatory and market forces paired with a growing body of scientific research have driven the market to seek alternatives to certain traditional preservatives as product formulators face the challenge of balancing product preservation and regulatory requirements with competing consumer interests and health concerns. We summarize below some of the key regulatory and market activities focused on the use of preservatives in personal care products.

Regulatory Landscape UNITED STATES (NATIONAL)

Food and Drug Administration (FDA)

Under the Federal Food, Drug, and Cosmetic Act (FDCA), personal care products are primarily regulated as cosmetics, drugs, or both cosmetics and drugs (FDA, 2015a). Under the FDCA, formulators are prohibited from marketing "adulterated" products, which includes any product that has been contaminated or decomposed, rendering "it injurious to users under the conditions of use prescribed in the labeling thereof" (FDA, 2014). Products that are contaminated by microbial growth are considered adulterated per the FDCA definition.

As a general matter, FDA does not approve cosmetic products or ingredients before they enter the market with the exception of color additives that are not coal-tar hair dyes. The FDA may choose to review products or ingredients. There are a few cosmetic ingredients that are prohibited by regulation (FDA, 2015b). The FDA has regulated the following ingredients with antimicrobial properties for use in personal care products (some of which were previously used as preservatives) (Steinberg, 2012):[5]

- Hexachlorophene (21 CFR 250.250)
- Mercury compounds (21 CFR 700.13)
- Bithional (21 CFR 700.11)
- Halogenated salicylanides (21 CFR 700.15)

It is the legal responsibility of companies who make or sell personal care products to ensure the safety of their products and ingredients including that the product is adequately preserved.

A manufacturer may use a particular ingredient in a product if that ingredient and product are safe under the conditions of use as determined by the manufacturer; the product is compliant with labeling requirements; and the ingredient and product are not otherwise adulterated (FDA, 2014). This requires that a product does not contain pathogenic microorganisms and has a low density of non-pathogenic microorganisms (Steinberg, 2012). The FDA can take action if products are not in compliance with the law.

The FDA has the authority to perform post-market testing or analysis of ingredients and products during cosmetic facility inspections and inspections of imported cosmetic products. The FDA may also respond to complaints regarding adulterated products and investigates concerns about the safety of specific preservative ingredients.

All told the personal care product sector is largely self-regulating in the U.S.

Cosmetic Ingredient Review

The Cosmetic Ingredient Review (CIR)[6], a U.S.-based and industry-funded organization convenes an Expert Panel of scientists and medical experts to review cosmetic ingredient safety and recommend any potential restrictions. Expert Panel ingredient assessments are based on available literature and industry-submitted data. Assessments are provided in a compendium for purchase and freely on CIR's webpages.

5 For a list of other cosmetic ingredients that the FDA has prohibited or restricted, current as of November 2011, see here: http://www.cir-safety.org/sites/default/files/prohibitedrestrictedbyFDA%2011-30-2011.pdf

6 http://www.cir-safety.org/

Regulatory Landscape UNITED STATES (STATE)

Minnesota Statutes Section 325F.176-325F.178

Minnesota Statutes Section 325F.176 – 325F.178 bans formaldehyde and chemicals that release formaldehyde (formaldehyde releasers such as DMDM hydantoin) in certain children's products sold in the state of Minnesota.[7] Beginning in 2014, product manufacturers and wholesalers were prohibited from selling any applicable children's products that intentionally contain formaldehyde or chemicals that will degrade under "normal conditions of temperature and pressure" to release formaldehyde at levels greater than 0.05%. Beginning in 2015 the same prohibition applied to retailers. The statute also requires that product manufacturers not replace formaldehyde or formaldehyde-releasers in applicable children's products with known or suspected with a high degree of probability to cause developmental toxicity, cancer, reproductive toxicity, endocrine disruption, or systemic toxicity as determined by authoritative bodies.

Washington State Children's Safe Product Act

The Washington State Children's Safe Product Act (CSPA) and accompanying reporting rule establish reporting requirements for children's products that contain one or more chemicals found on the Washington state list of Chemicals of High Concern to Children (CHCC). Chemicals included on the CHCC list meet specified criteria related to hazard and exposure concerns for a child or developing fetus.[8] The CHCC includes chemicals that may be used as preservatives in children's products, such as formaldehyde and several parabens (WA DoH, 2011a,b). Product manufacturers are required to report, by product category, the amount and function of a CHCC chemical present in a product or component of a product. The product categories covered by the reporting rule are based on the definition of children's products established in the CSPA (WSDE, 2013). Reported data are published, updated, and searchable on the Washington Department of Ecology website.[9]

7 https://www.revisor.mn.gov/statutes/?id=325F (see 325F.176 - 325F.178)

8 http://apps.leg.wa.gov/RCW/default.aspx?cite=70.240.030

9 http://www.ecy.wa.gov/programs/hwtr/RTT/cspa/

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European Union

The safety of personal care products like soap, shampoo, and makeup, is the responsibility of the product manufacturer under EU Cosmetics Regulation 1223/2009[10] ("Cosmetics Regulation"), which came into force on July 11, 2013. All such products must be registered through the Cosmetic Products Notification Portal (CPNP) before entering the market in the EU. The product manufacturer must ensure that the product has undergone a safety assessment following the requirements identified in Annex I of the Cosmetics Regulation prior to placing the product on the market.

The additional Annexes to the Cosmetics Regulation set forth specific lists of permissible, restricted, or prohibited chemicals and classes of chemicals: chemicals that are prohibited in cosmetic products (Annex II), chemicals that are allowed for use with certain restrictions (Annex III), colorants allowed or allowed provisionally in products (Annex IV), permitted preservatives (Annex V), and UV filters which cosmetic products may contain (Annex VI).

The Cosmetics Regulation defines preservatives as "substances which are exclusively or mainly intended to inhibit the development of microorganisms in the cosmetic product" (EC, 2009). Currently, Annex V includes 57 permitted preservatives for cosmetic products, though the

10 http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R1223

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actual number of individual preservative chemicals in Annex V is much greater as many entries include multi salts or esters of substances.[11] Annex V also stipulates conditions of use that include maximum concentration of use; specific concentration limitations based on product type and/or body parts on which a product is applied; prohibitions on use in specific product types (e.g., use in children's products) and other considerations, such as purity criteria. Annex I requires that the party responsible for the safety of the product submit a qualitative and quantitative description of the composition of the cosmetic product, including the identity and intended function of all chemicals comprising the product formulation. Only chemicals included on Annex V are allowed as active preservative ingredients. However, opportunities to circumvent the use of only permitted preservatives per the Cosmetics Regulation can result from the use of multifunctional chemicals where the primary function of these ingredients is not to inhibit the growth of microorganisms yet they still exhibit biostatic properties. This has enabled some companies to claim their products as "preservative-free" (Schulke, 2015).

The European Commission Scientific Committee on Consumer Safety (SCCS) is responsible for the safety evaluation of chemicals to be added to the Annexes, including preservatives (EC, 2015a). The chemical manufacturer must submit a toxicological dossier to the SCCS, which then performs a hazard identification, dose-response assessment, exposure assessment, and risk characterization of the submitted chemical.[12] The SCCS issues scientific opinions on the chemicals in question. These opinions are considered and recommendations are often followed, but the adoption of a recommendation is not required by law. In particular, these opinions inform decisions by the European Commission for chemical listing on Annexes and other decisions related to risk management and hazard communication.

Canada

The safety of cosmetic products in Canada is regulated under the Food and Drugs Act (R.S.C., 1985, c. F-27) and the Cosmetic Regulations (C.R.C., c. 869). The "Cosmetic Ingredient Hotlist" (Hotlist) identifies substances that are restricted (e.g., concentration limits, product-type exclusions, and labeling requirements) or prohibited for use in cosmetic products, pulling from stipulations laid out in both the Food and Drugs Act and Cosmetics Regulation (HC, 2014). Health Canada is the entity responsible for maintaining this list. In addition to its own reviews, Health Canada consults ingredient assessments and decisions made by other authoritative bodies, for example, the Scientific Committee on Consumer Safety (SCCS) in the EU. Additions and updates to the Hotlist occur via a formal consultation process that allows for stakeholder input. Notably, Health Canada has also set specific conditions and limitations for making "free of" ingredient claims on products including for preservatives (Steinberg, 2012).

Japan

In Japan, personal care products and ingredients, including preservatives, are regulated by the Ministry of Health, Labour, and Welfare (MHLW) under the Pharmaceutical Affairs Law (Rannou, 2015). Under the Pharmaceutical Affairs Law, product manufactures and importers are responsible for ensuring the safety of their products which in part requires product testing by MHLW-designated laboratories. A Japanese regulation pursuant to the Pharmaceuticals Affairs Law, the Standard for Cosmetics, defines ingredients that are prohibited or restricted for use in products, as well as cosmetic ingredients that are permitted for use within particular functional classes (e.g., preservatives) (Rannou, 2015). The Standard for Cosmetics list of restrictions and permitted substances set stricter standards than other authorities in many cases. Also under the Standard, product manufacturers and importers must submit specific notifications to specified state authorities prior to introducing the cosmetic product to the market (ChemLinked, 2015). As part of this notification process, submitters must include testing results that verify a product does not contain prohibited ingredients and that permitted ingredients are in compliance with relevant restrictions.

11 For a full list of preservatives in Annex V, see: http://ec.europa.eu/growth/tools-databases/cosing/index.cfm?fuseaction=search.results&annex_v2=V&search

12 http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_006.pdf

Market-Based Activities

In addition to the regulatory activities directed at the use of preservatives in personal care products, a variety of consumer campaigns and market actions have prompted market deselection of certain preservative ingredients and a push for safer, effective alternatives. A handful of market campaigns are described below.

The Campaign for Safe Cosmetics, a coalition organized by the Breast Cancer Prevention Partners, pursues a number of initiatives including public education, policy advocacy, and corporate engagement, to urge the personal care industry to stop the use of certain chemicals and ultimately, drive safer products. The Campaign has created *Red Lists* of ingredients to avoid in personal care products. These *Red Lists* include commonly used preservatives, such as parabens and formaldehyde releasers (Campaign for Safe Cosmetics Undated). The Campaign for Safe Cosmetics launched the "Cosmetics Without Cancer" Campaign in early 2015, for consumers to petition select product manufacturers to remove chemicals linked to cancer from their cosmetic products. Formaldehyde-releasing preservatives were among the targeted compounds. The Campaign for Safe Cosmetics reports that several companies targeted by the Campaign have responded to the petition and proceeded with reformulations of their products to address consumer concerns (Campaign for Safe Cosmetics, 2014).

The Mind the Store campaign, launched by the Safer Chemicals, Healthy Families coalition, has generated a list of slightly over 100 chemicals of concern, the *Hazardous Hundred List*, based on U.S. and international authoritative listings of chemicals that have been determined to present hazard and/or risk. Mind the Store advocates for retailers to remove the *Hazardous Hundred List* chemicals from the products they sell. The *List* includes parabens for their endocrine disrupting activity (Safer Chemicals, undated).

International market campaigns have also focused on personal care products ingredients. For example, Environmental Defence is a Canadian environmental action organization focused on a variety of sustainability issues including reducing exposures to harmful chemicals. Environmental Defence's "Just Beautiful Pledge" features a toxic 10 list of harmful ingredients for consumers to avoid and includes preservatives, i.e., formaldehyde-releasing agents, parabens, BHA & BHT, and triclosan (Environmental Defence, 2016).

In addition to advocacy led market-based activities, certain product manufacturers and retailers are increasingly pursing initiatives to reduce and eliminate toxic chemicals from their products and shelves respectively. Certain preservatives have been among the targets of such initiatives. Notably, Walmart's 2016 progress report on its Sustainable Chemistry Policy identified eight high priority chemicals, four of which are preservatives: butylparaben, propylparaben, formaldehyde, and triclosan (Walmart, 2016). Target's 2017 chemicals policy identified a handful of chemicals for elimination by 2020 in its beauty, baby care, personal care and household cleaning product categories including the preservatives propylparaben, butylparaben, and formaldehyde-donors (Target, 2017).

APPENDIX B

PIP Preservative Profiles

Brief profiles of the 16 selected PIP preservatives are provided. The profiles include information regarding the preservatives' function in products (including and in addition to preservation), product use, microbial activity, formulation considerations, and regulatory and related information.

To compile regulatory and related information, the EU Cosmetics Regulation, Health Canada's Cosmetic Ingredient Hotlist and Japan Standard for Cosmetics were consulted. If a chemical is listed on the EU Cosmetics regulation Annex V "List of Preservatives Allowed in Cosmetics," it is permitted as a preservative ingredient in cosmetic products in the EU and is noted in the profile. If a ban or restriction exists for a specific chemical in the EU, the chemical is found on Annex II or III, respectively, and this is provided as well. Absence of a listing on EU Annex V indicates that a chemical is not permitted to be used as a preservative; absence of a listing on Annex II or III indicates a chemical is not otherwise banned or restricted in personal care products. Applicable activities from the following state departments were also searched: WSDE (2011); CA OEHHA (2015); ME DEP (2012); MN DH (2013); CA DPH (2015); and CA DTSC (2015). Finally, synopses of Cosmetic Ingredient Review (CIR) Expert Panel opinions are provided. Regulatory and related information from these sources is noted in each chemical profile where available.[13]

13 Not including the regulatory information, the following primary resources were searched to compile the preservative profiles unless noted otherwise: Steinberg (2012), EC (2015b), chemical supplier information provided exclusively via UL Prospector (https://www.ulprospector.com/en/na/PersonalCare), and the NIH hazardous substances data bank (https://www.nlm.nih.gov/pubs/factsheets/hsdbfs.html). The profile information is accurate as of January 2016, however resources used to compile the profiles change and information may be outdated. Note the information presented here does not reflect the view of Environmental Defense Fund and is strictly a digest of what is reported in the referenced resources.

BENZYL ALCOHOL (CAS# 100-51-6)

Overview

- Functions: Fragrance component, preservative, solvent, viscosity-controlling (EC, 2015b); flavoring component, plasticizer, degreasing agent (HSDB, 2009).
- Microbial Activity: Most active against gram-positive bacteria, moderately active against gram-negative bacteria and yeast/mold (Siegert, 2014).
- Product Uses: Cosmetics[14], food, over the counter drugs, inks and paint (Steinberg, 2012).
- Formulation Considerations (Steinberg, 2012):
  - Most effective below pH 7;
  - Inactivated by nonionics;
  - Soluble in water;
  - Will oxidize to benzaldehyde, which has a strong odor, therefore antioxidants are co-incorporated into formulations.

14 The FDA defines "cosmetics" by their intended use, as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance" [FD&C Act, sec. 201(i)]. The EU Cosmetics Regulation stipulates that the determination of a product as a "cosmetic" is done on a case-by-case basis; section (7) of the Cosmetics Regulation provides a list of possible products (EC, 2009). The CIR defines "cosmetics" as "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles, except that it shall not include soap" (CIR, 2010).

BENZYL ALCOHOL (CAS# 100-51-6)

Regulatory and Related Information

- Listed in Section 34 of EC Cosmetics Regulation No. 1223/2009 Annex V: Preservatives allowed for use in cosmetics:
  - Maximum concentration in ready for use preparation: 1.0%.
- Listed in Section 45 of EC Cosmetics Regulation No. 1223/2009Annex III: Substances which cosmetic products must not contain except subject to the restrictions laid down:
  - May be used for uses other than as a preservative in certain product types (i.e., as a solvent or fragrance); the purpose has to be apparent from the presentation of the product;
  - Requirements due to identification as EU Fragrance Allergen (SCCS, 2012): The presence of the substance must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on products and 0.01% in rinse-off products;
- Reviewed by CIR Expert Panel, as amended (CIR, 2011c):
  - Safe in current practices of use and concentration[15] (S);[16]
  - Use concentrations for S conclusion: 0.000006 – 10%.

15 The CIR Expert Panel bases its safety determinations on the expected use of each ingredient in cosmetics. The Panel determines expected use, including use concentrations, based on data received from the FDA through its Voluntary Cosmetic Registration Program (VCRP) as well as by industry submissions in response to a survey conducted by the Personal Care Products Council (PCPC) on the maximum reported use concentrations by product category (CIR, 2010).

16 The CIR Expert Panel determines, for each cosmetic ingredient, whether it is: safe in the present practices of use and concentration (S), safe for use in cosmetics with qualifications (SQ), the available data are insufficient to support safety (I), the available data are insufficient to support safety but the ingredient is not in current use (Z), the ingredient is unsafe for use in cosmetics (U), the available data are insufficient and the ingredients use in cosmetics is not supported (UNS).

CAPRYLHYDROXAMIC ACID (CAS# 7377-03-9)

Overview

- Functions: Chelant[18] (EC, 2015b) (chelates with $Fe2^{+}$ and $Fe3^{+}$ ions); preservative (Steinberg, 2012).
- Product Uses: Cosmetics (Inolex, 2013a).
- Microbial Activity: Most active against mold; also active against gram-positive and negative bacteria and yeast (Hase et al. 1971; Ammendola et al., 2009; Bravo and Lazo, 1993; Steinberg, 2012).
- Formulation considerations (Inolex, 2013a):
  - Suitable for pH 2-8;
  - May interact with residual iron found in certain clay-type compounds which can result in a very mild orange color or color shift and decreased preservative activity in products.

Regulatory and Related Information: None available in searched sources.

17 "Reacts and forms complexes with metal ions which could affect the stability and/or appearance of cosmetics" (EC, 2015b)

CAPRYLYL GLYCOL (CAS# 1117-86-8)

Overview

- Functions: Emollient[18], hair-conditioning agent[19], humectant[20], skin-conditioning agent[21] (EC, 2015b); viscosity agent, preservative (CIR, 2011b).
- Product Uses: Cosmetics (Steinberg, 2012).
- Microbial Activity: Active against gram-positive and gram-negative bacteria; moderate activity for yeasts/molds (Dr. Straetmans, 2008); also able to improve the effectiveness of other preservatives at concentrations lower than their typical use level.
- Formulation Considerations (Steinberg, 2012):
  - Active in broad pH range;
  - Inactivated by dilution;
  - Insoluble in water;
  - Poorly active in surfactant systems;
  - May affect the viscosity and stability of certain emulsions as it is a secondary emulsifier.

Regulatory and Related Information

- Reviewed by CIR Expert Panel (CIR, 2011b):
  - Safe in the current practices of use and concentration (S);
  - Use concentration for S conclusion: 0.00003 - 5% for dermal contact personal care products;
  - Potential skin penetration enhancers.

18 "Softens and smooths the skin" (EC, 2015b)

19 "Leaves the hair easy to comb, supple, soft and shiny and/or imparts volume, lightness, gloss, etc." (EC, 2015b)

20 "Holds and retains moisture" (EC, 2015b)

21 "Maintains the skin in good condition" (EC, 2015b)

DMDM HYDANTOIN (CAS# 6440-58-0)

Overview

- Functions: Preservative (EC, 2015b).
- Microbial Activity: Good activity for gram positive and gram negative bacteria; moderately active against yeasts and molds (Siegert, 2014).
- Product Uses: Personal care products, paints, coatings and household products, adhesives, polymer solutions, metal working products and clay slurries (Steinberg, 2012).
- Formulation considerations (Steinberg, 2012):
  - Active at pH 3-9;
  - Water soluble, low oil solubility

Commercially available for cosmetics in aqueous solution, oil solution, or as an anhydrous powder.

Regulations and Related Information

- Listed in Section 33 of EC Cosmetics Regulation No. 1223/2009 Annex V: Preservatives allowed for use in cosmetics:
  - Substance name: 1,3-Bis(hydroxymethyl)-5,5-dimethylimidazolidine-2,4-dione:
  - Maximum concentration in ready for use preparation: 0.6%;
  - If the concentration of free formaldehyde exceeds 0.05% in the finished product, the product must be labeled “contains formaldehyde”.
- Minnesota Ban on Formaldehyde Releasers in Children’s Product (also see Appendix A).
- Reviewed by CIR Expert Panel (CIR, 1988):
  - Safe in current practices of use and concentration (S);
  - Use concentration for S conclusion: Up to 1% for dermal contact cosmetics.

ETHYLENEDIAMINIETETRAACETIC ACID (EDTA) (CAS# 60-00-4)

Overview

- Functions: Chelant (EC, 2015b); antioxidant, detergent, bleaching agent, etching agent (HSDB, 2012).
- Microbial Activity: Reduces availability of iron for microbial growth; not active against gram-positive bacteria; enhances activities of antibacterial agents particularly against drug-resistant gram-negative microbes by increasing the permeability of cellular membranes; prevents growth of yeast and molds in zinc-dependent fashion (Brul et al., 1997).
- Product Uses: Cosmetics, food, medicine, cleaning (Steinberg, 2012).
- Formulation Considerations (Steinberg, 2012):
  - EDTA is mostly insoluble in water, preferred incorporation through its salts (Disodium EDTA, Trisodium EDTA, and Tetrasodium EDTA);
  - Aqueous solution of EDTA contains by-products of formalin and sodium cyanide, however, the purified and dried form of aqueous EDTA forms the salts which have had the impurities removed.

Regulatory and Related Information

- Reviewed by CIR Expert Panel (CIR, 2002):
  - Safe in current practices of use and concentration (S);
  - Use concentration for S conclusion: Up to 2%.

ETHYLHEXYLGLYCERIN (CAS# 70445-33-9)

Overview

- Functions: Skin-conditioning agent (EC, 2015b); Solvent and enhancer for other preservatives (Steinberg, 2012).
- Product Uses: Personal care products (emulsions only) (Inolex, 2013a).
- Microbial Activity: Most active against gram positive bacteria; boosts the efficacy of traditional preservatives and acts as an antimicrobial stabilizer (Steinberg, 2012; Leschke and Siegert, 2008).
- Formulation Considerations (Steinberg, 2012):
  - Active over broad pH range;
  - No published inactivators;
  - Poorly soluble in water.

Regulatory and Related Information

- Reviewed by CIR Expert Panel (CIR, 2011a; 2013):
  - Safe in the current practices of use and concentration (S).
  - No use concentration identified for S conclusion, but used in products at concentrations up to 8% (as of 2011).

GLUCONOLACTONE (CAS# 90-80-2)

Overview

- Functions: Chelant; skin-conditioning agent (EC, 2015b); flavoring ingredient (Spectrum, 2015a).
- Microbial Activity: The active agent, gluconic acid, is able to control microbial growth by reducing pH to a level that inhibits putrefactive and toxigenic bacteria growth (Lemay et al., 2000).
- Product Uses: Cosmetics (EC, 2015b); food (Spectrum, 2015b).
- Formulation considerations: No information available in searched sources.

Regulatory and Related Information: None available in searched sources.

IODOPROPYNYL BUTYLCARBAMATE (IPBC) (CAS# 55406-53-6)

Overview

- Functions: Preservative (EC, 2015b); fungicide (Steinberg, 2012).
- Microbial Activity: Very active against yeast and mold, inadequate activity against bacteria (Steinberg, 2012).
- Product Uses: Personal care products, industrial applications (Steinberg, 2012)
- Formulation Considerations (Steinberg, 2012):
  - Active at pH 2-9, slowly hydrolyzes at alkaline pH;
  - Inactivated by strong reducing agents, acids, and bases;
  - Low water solubility, soluble in propylene glycol.

Regulatory and Related Information

- Listed in Section 56 of EC Cosmetics Regulation No. 1223/2009 Annex V: Preservatives allowed for use in cosmetics with the following restrictions:
  - Maximum concentration in ready for use preparation:
    - Rinse-off products: 0.02%; not to be used in rinse-off products for children under the age of 3 except in bath products, shower gels, and shampoos;
    - Leave-on products: 0.01%; not to be used in body lotion and body cream; not be used in leave-on product for children under the age of 3;
    - Deodorants/antiperspirants: 0.0075%;
    - Not to be used in oral and lip products.
  - Warning labels required. Wording of warnings:
    - For rinse off products other than bath products/ shower gels and shampoo, which might be used for children under 3 years of age: “Not to be used for children under 3 years of age”;
    - For leave on products and deodorants/anti-perspirants which might be used on children under 3 years of age: “Not to be used for children under 3 years of age”.
- Reviewed by CIR Expert Panel (CIR, 1998):
  - Safe for use in cosmetics with qualifications (SQ): Safe for use at 0.1%; should not be used in products intended to be aerosolized;
  - Generally used at less than 0.0125%.
- Additional Regulatory Information:
  - Allowed in Japan in cosmetics up to 0.02%.

LACTOBACILLUS FERMENT (CAS# 1686112-36-6)

Overview

- Functions: Skin-conditioning agent (EC, 2015b); skin and hair conditioning agent, preservative (Active Micro, 2014).
- Microbial Activity: Active against gram positive and gram negative bacteria, moderate activity for yeasts and molds (Active Micro, 2014).
- Product Uses: Cosmetics.
- Formulation Considerations (Active Micro, 2014):
  - Active at pH 3-8;
  - No identified inactivators;
  - Water soluble.

Regulatory and Related Information: None available in searched sources.

METHYLISOTHIAZOLINONE (MIT) (CAS# 2682-20-4)

Overview

- Functions: Preservative (EC, 2015b).
- Microbial Activity: Good to moderate activity for gram positive and gram negative bacteria, yeasts, and molds (Siegert, 2014).[22]
- Product Uses: Personal care products, cleaning products, industrial applications (Ashland, undated).
- Formulation Considerations (Steinberg, 2012):
  - Active at pH 2-10;
  - Reacts and loses activity with: bisulfites, secondary amines, strong nucleophiles;
  - Soluble in water.

Regulatory and Related Information

- Listed in Section 57 of EC Cosmetics Regulation No. 1223/2009 Annex V: Preservatives allowed for use in cosmetics:
  - Maximum concentration in ready for use preparation: 0.01%; however, a ban on MIT in leave-on applications is set to go into effect in 2017;
  - Maximum concentration in mixture of Methylchloroisothiazolinone (MCI) and Methylisothiazolinone in ready for use preparations: 0.0015% (of a 3:1 mixture of MCI:MIT);
  - SCCS (2015): Use of MIT in rinse-off applications should be lowered to 0.0015% due to sensitizing effects.
- Reviewed by CIR Expert Panel (CIR, 2014a):
  - Safe for use in cosmetics with qualifications (SQ): Safe at concentrations up to 100 ppm (0.01%) in rinse-off products and in leave-on products when formulated to be non-sensitizing, which may be determined based on quantitative risk assessment (QRA).
- Additional regulatory information:
  - Allowed preservative in Japan at concentrations equal or less than 0.01%; not allowed in any products applied to mucosa;
  - Restricted in Health Canada's Cosmetic Ingredient Hotlist:
    - » MIT by itself is allowed for use as a preservative in concentrations equal to or less than 0.01%;
    - » MCI may only be used when in combination with MIT. The mixture is banned in leave on products and restricted to 0.0015% in rinse off products.

22 Siegert (2014) notes that the 100 ppm restriction on MIT will render it unable to protect cosmetics

PHENOXYETHANOL (CAS# 122-99-6)

Overview

- Functions: Preservative (EC, 2015b); perfume fixative (CIR, 2014a); solvent, insect repellent (Steinberg, 2012).
- Microbial Activity: Most active against gram-negative bacteria; moderate activity for gram-positive bacteria and yeasts/molds (Siegert, 2014).
- Product Uses: Cosmetics, fragrances, insect repellent, paint strippers, drug products, adhesives (Steinberg, 2012; CIR, 2014a).
- Formulation Considerations (Steinberg, 2012):
  - Active over pH range 3-10;
  - Inactivated by highly ethoxylated compounds;
  - Soluble in water, propylene glycol, and glycerin;
  - Purity level of ingredient activity can vary in commercial products, with several different impurities possible. In particular, the level of the impurity free phenol, which is an irritant, is important to consider;
  - Phenoxyethanol may increase bacterial load in anionic surfactant solutions if the water is not saturated with phenoxyethanol, as a low level of the compound can serve as a nutrient for bacteria.

Regulatory and Related Information

- Listed in Section 29 of EC Cosmetics Regulation No. 1223/2009 Annex V: Preservatives allowed for use in cosmetics:
  - Maximum concentration in ready for use preparations: 1%.
- Reviewed by CIR Expert Panel (CIR, 2014a):
  - Safe in the current practices of use and concentrations (S);
  - Use concentration for S conclusion: 0.0002 to 1%.
- Additional regulatory information:
  - Japan has approved for use at a maximum concentration of 1% without restrictions for all personal care products.

PIROCTONE OLAMINE (CAS# 68890-66-4)

Overview

- Functions: Preservative (EC, 2015b); anti-dandruff agent (Clariant, 2004).
- Microbial Activity: Good activity against gram-positive bacteria, yeasts and molds; moderate activity for gram negative bacteria (Clariant, 2004;
  Siegert, 2014).
- Product Uses: Cosmetics, over-the-counter drugs (anti-dandruff hair products) (Clariant, 2004).
- Formulation Considerations: No information available in searched sources.

Regulations and Related Information

- Listed in Section 35 of EC Cosmetics Regulation No. 1223/2009 Annex V: Preservatives allowed for use in cosmetics:
  - Substance group: 1-Hydroxy-4-methyl-6-(2,4,4-trimethylpentyl)-2 pyridon and its monoethanolamine salt;
  - Maximum concentration in ready for use preparation for rinse-off products: 1.0%;
  - Maximum concentration in ready for use preparation for other products: 0.5%.
- Listed in Section 61 of EC Cosmetics Regulation No. 1223/2009 Annex III: Substances which cosmetic products must not contain except subject to the restrictions laid down:
  - Substance group: Monoalkylamines, monoalkanolamines and their salts;
  - Maximum concentration in ready for use preparation: Maximum secondary amine content: 0.5%;
  - Other:
    - » Do not use with nitrosating systems;
    - » Minimum purity: 99%;
    - » Maximum secondary amine content: 0.5% (applies to raw materials);
    - » Maximum nitrosamine content: 50 microgram/kg;
    - » Keep in nitrite-free containers.

PROPYLPARABEN (94-13-3)

Overview

- Functions: Preservative (EC, 2015b).
- Microbial Activity: Good activity against gram-positive bacteria, yeasts and molds; moderate activity against gram-negative bacteria (Seigert, 2014).
- Product Uses: Cosmetics, food (HSDB, 2007).
- Formulation Considerations (Steinberg, 2012):
  - No activity above pH 6 as it is in inactive salt form;
  - Inactivated by raising the pH; the method of addition of the paraben to formulations will affect inactivation;
  - Water soluble;
  - Only active in the water phase, not active in the oil phase.

Regulatory and Related Information

- Listed in Section 12 of EC Cosmetics Regulation 1223/2009 Annex V: Preservatives allowed for use in cosmetics:
  - Listed in substance group: Butyl 4-hydroxybenzoate and its salts, Propyl 4-hydroxybenzoate and its salts;
  - Maximum concentration in ready for use preparation:
    - 0.14% (as acid);
    - Aggregate concentration of butyl- and propylparaben and their salts cannot exceed 0.14%;
    - Aggregate concentration of substances in substance group[23] cannot exceed 0.8% (as acid).
  - Additional conditions:
    - Not to be used in leave-on products designed for application on the nappy area of children under three years of age;
    - Required wording of warning labels for conditions of use for leave-on products designed for children under three years of age: "Do not use on the nappy area".
- Maine Chemical of High Concern (ME DEP, 2012).
- Minnesota Chemical of High Concern (MN DH, 2013).
- Washington State Department of Ecology Chemical of High Concern to Children (WSDE, 2011).
- CA DTSC Informational List of Candidate Chemicals (CA DTSC, 2015).

23 The substance group includes all substances listed in entries 12 and 12a in Annex V, which includes: butylparaben, propylparaben, sodium propylparaben, sodium butylparaben, potassium butylparaben, potassium propylparaben, 4-hydroxybenzoicacid, methylparaben, potassium ethylparaben, potassium paraben, sodium methylparaben, sodium ethylparaben, ethylparaben, sodium paraben, potassium methylparaben, and calcium paraben.

- Reviewed by CIR Expert Panel (CIR, 2008):
  - Safe in the current practices of use and concentrations (S);
  - Use concentration for S conclusion: Up to 0.4% if used alone; maximum aggregate concentration of parabens in a product is 0.8%.

SORBIC ACID (CAS# 110-44-1)

Overview

- Functions: Preservative (EC, 2015b).
- Microbial Activity: Most active against yeast and mold (fungistatic) and poorly active against bacteria (CIR, 2012).
- Product Uses: Cosmetics, food, pharmaceuticals (Steinberg, 2012); Animal feeds, tobacco (HSDB, 2002).
- Formulation Considerations (CIR, 2012; Steinberg, 2012):
  - Active at pH values up to 6.5;
  - Inactivated by raising the pH;
  - Poorly soluble in water;
  - Subject to oxidation.

Regulatory and Related Information

- Listed in Section 4 of EC Cosmetics Regulation No. 1223/2009 Annex V: Preservatives allowed for use in cosmetics:
  - Listed in substance group: Hexa-2,4-dienoic acid and its salts;
  - Maximum concentration in ready for use preparation: 0.6% (acid).
- Reviewed by CIR Expert Panel (CIR, 1988):
  - Safe in the current practices of use and concentration (S);
  - Use concentration for S conclusion: up to 5% for dermal contact personal care products.
- Permitted in Japan in all applications up to 0.5%.

SORBITAN CAPRYLATE (CAS# 60177-36-8)

Overview

- Functions: Emulsifier (EC, 2015b); viscosity controlling agent, assists efficacy of preservatives (Clariant, 2012).
- Microbial Activity: Demonstrates efficacy against gram-positive bacteria; not active against gram-negative bacteria and undetermined for yeasts/molds (Clariant, 2012; Wagh et al., 2012).
- Product Uses: Personal care products (Clariant, 2012).
- Formulation Considerations (Clariant, 2012):
  - Active at pH 4-8;
  - No identified inactivator;
  - Poor solubility in water.

Regulatory and Related Information

- Reviewed by CIR Expert Panel (CIR, 2014b):
  - Safe in current practices of use and concentration (S);
  - Use concentration for S conclusion: up to 5% for dermal contact personal care products.

UNDECYLENIC ACID (CAS# 112-38-9)

Overview

- Functions: Cleansing[24], emulsifier, preservative, surfactant[25] (EC, 2015b); modifying agent, fungistat (Bingham and Cohrssen, 2012).
- Microbial Activity: Active against fungi (Spectrum, 2015b); no activity against bacteria (Siegert, 2014).
- Product Uses: Cosmetics, pharmaceuticals (over-the-counter drugs) (Spectrum 2015ba); plasticizer and lubricant additive (Bingham and Cohrssen, 2012).
- Formulation considerations: No information available in searched sources.

Regulations and Related Information

- Listed in Section 18 of EC Cosmetics Regulation No. 1223/2009 Annex V: Preservatives allowed for use in cosmetic products:
  - Substance group: Undec-10-enoic acid and its salts;
  - Maximum concentration in ready for use preparations: 0.2% (as acid).
- Following CIR procedure, CIR deferred evaluation because the safety of this ingredient has been assessed by the FDA (Cosmetics Info, undated).
- Additional regulatory information:
  - Approved by the FDA as an antifungal ingredient in topical antimicrobial drug products for over-the-counter human use, provided that the total concentration of undecylenate in formulation is 10 – 25% (FDA, 2002).

24 "Helps to keep the body surface clean" (EC, 2015b)

25 "Lowers the surface tension of cosmetics as well as aids the even distribution of the product when used" (EC, 2015b)

APPENDIX C Overview of GreenScreen® for Safer Chemicals Method

GreenScreen® for Safer Chemicals is a comparative hazard assessment method designed to efficiently and consistently characterize hazards for human health and environmental fate and toxicity endpoints using a robust literature search approach that builds from authoritative and screening sources (CPA, 2015). The GreenScreen® method has been used by many companies as well as advocacy groups to evaluate and make decisions around the use of chemicals in a variety of product types such as electronics, building materials, and textiles (Eisenberg, 2013; GC3, 2013; Heine, 2013; Material IQ, 2016). It has also been used as a hazard assessment method for alternative assessments by several state regulatory programs (WA DoH, 2008; MN DEP 2012), and is recognized as the hazard assessment platform for several standards and ecolabels (USGBC, 2008; ZDHC, 2013; CPA, 2015).

The GreenScreen® hazard assessment method is publically available and involves an evaluation of 18 human health, environmental and physical hazard endpoints (CPA, 2011; 2012; 2013). The human health endpoints are subdivided into 1) Group I Human Health hazards (carcinogenicity, mutagenicity, reproductive toxicity, developmental toxicity, and endocrine activity), which according to the developers, represent hazards that lead to chronic or life-threatening health effects that may result from low dose exposures, and 2) Group II Human Health hazards (acute toxicity, systemic toxicity-single dose, neurotoxicity-single dose, skin irritation, and eye irritation) and II* (systemic toxicity-repeated dose, neurotoxicity-repeated dose, skin sensitization, and respiratory sensitization). The environmental endpoints include ecotoxicity (acute aquatic and chronic aquatic) and environmental fate (persistence and bioaccumulation), while the physical hazard endpoints include reactivity and flammability (CPA, 2013).

Figure C1: Sample GreenScreen® Hazard Assessment Table

Group I Human Health					Group II and II* Human Health									Ecotox		Fate		Physical	
C	M	R	D	E	AT	ST		N		SnS*	SnR*	IrS	IrE	AA	CA	P	B	Rx	F
						s	r*	s	r*										
L	L	L	*M*	DG	M	DG	L	*M*	*H*	H	DG	L	H	L	L	vL	vL	*L*	L

Evaluation of a chemical across each of the hazard endpoints involves both a review of authoritative lists[26] and available data.[27] Following the compilation and review of data, a hazard score is assigned (i.e., Very Low (vL), Low (L), Moderate (M), High (H), or Very High (vH)) to each endpoint according to the GreenScreen® method, which is largely based on criteria outlined in the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (UN, 2015; CPA, 2012). In addition, a confidence level (low or high) is assigned to the hazard score to indicate the quality and robustness of the dataset leading to the score. The confidence level of the score is assigned based on the quantity, quality (both in terms of experimental design and reporting), and type (e.g., experimental or modeled, in vitro or in vivo) of available data and overall ability of the dataset to support the hazard classification. Scores assigned with high confidence are reported in bold, while score assigned with reduced confidence are reported in italics. A Data Gap (DG) is assigned when data are lacking or insufficient to assign an endpoint hazard score.

26 GreenScreen® specified authoritative lists can be found at http://www.greenscreenchemicals.org/

27 Data considered in the evaluation include experimental data for the target chemical and surrogates as well as modeled and estimated data

Finally, an overall GreenScreen® Benchmark™ score ranging from 1 (Avoid—Chemical of High Concern) to 4 (Prefer—Safer Chemical) is assigned based on the individual hazard endpoint scores as outlined in the GreenScreen® method (CPA, 2011). The Benchmark™ score is intended to serve as a high-level indicator of hazard, while the individual hazard scores and data summaries for each endpoint provide a deeper level of hazard characterization for comparison and decision-making.

GreenScreen® for Safer Chemicals v1.3
GreenScreen Benchmarks™

GS BENCHMARK 4

ABBREVIATIONS
- **P** Persistence
- **B** Bioaccumulation
- **T** Human Toxicity and Ecotoxicity

GREENSCREEN BENCHMARK–4

Low P* + Low B + Low T (Ecotoxicity, Group I, II and II* Human) + Low Physical Hazards (Flammability and Reactivity) + Low (additional ecotoxicity endpoints when available)

Prefer—Safer Chemical

GREENSCREEN BENCHMARK–3

a. Moderate P or Moderate B
b. Moderate Ecotoxicity
c. Moderate T (Group II or II* Human)
d. Moderate Flammability or Moderate Reactivity

Use but Still Opportunity for Improvement

GREENSCREEN BENCHMARK–2

a. Moderate P + Moderate B + Moderate T (Ecotoxicity or Group I, II, or II* Human)
b. High P + High B
c. High P + Moderate T (Ecotoxicity or Group I, II, or II* Human)
d. High B + Moderate T (Ecotoxicity or Group I, II, or II* Human)
e. Moderate T (Group I Human)
f. Very High T (Ecotoxicity or Group II Human) or High T (Group II* Human)
g. High Flammability or High Reactivity

Use but Search for Safer Substitutes

GREENSCREEN BENCHMARK–1

a. PBT = High P + High B + [very High T (Ecotoxicity or Group II Human) or High T (Group I or II* Human)]
b. vPvB = very High P + very High B
c. vPT = very High P + [very High T (Ecotoxicity or Group II Human) or High T (Group I or II* Human)]
d. vBT = very High B + [very High T (Ecotoxicity or Group II Human) or High T (Group I or II* Human)]
e. High T (Group I Human)

Avoid—Chemical of High Concern

GREENSCREEN BENCHMARK–U
Unspecified Due to Insufficient Data

See Guidance (GreenScreen for Safer Chemicals Hazard Assessment Guidance) at http://greenscreenchemicals.org/method/method-documents for instructions.

Group I Human includes Carcinogenicity, Mutagenicity/Genotoxicity, Reproductive Toxicity, Developmental Toxicity (incl. Developmental Neurotoxicity), and Endocrine Activity. **Group II Human** includes Acute Mammalian Toxicity, Systemic Toxicity/Organ Effects-Single Exposure, Neurotoxicity-Single Exposure, Eye Irritation and Skin Irritation. **Group II* Human** includes Systemic Toxicity/Organ Effects-Repeated Exposure, Neurotoxicity-Repeated Exposure, Respiratory Sensitization, and Skin Sensitization. Immune System Effects are included in Systemic Toxicity/Organ Effects. **Ecotoxicity** includes Acute Aquatic Toxicity and Chronic Aquatic Toxicity.

* For inorganic chemicals, Persistence alone will not be deemed problematic. See Section 13.4 in this Guidance.

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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:

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March 6, 2018

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