Known and unknown persistent, bioaccumulative and toxic chemicals in the TSCA inventory

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'Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation'

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Summary

1. The TSCA inventory contains hundreds to thousands of chemicals that are persistent, bioaccumulative, and toxic at the same time. This clearly violates congressional intent. A major shortcoming of TSCA is the lack of information about chemical identities, properties and potential toxicity.
2. Due to the lack of efficient and forward-looking actions by EPA, the protection of the U.S. public happens only retroactively, after a significant exposure has already occurred. Recent examples include perflourinated compounds and brominated flame retardants which are ubiquitous in the U.S. population and the environment.
3. Within a reformed TSCA, the chemical industry should have a limited time during within which the information submitted to the EPA will be considered proprietary. After this time, information should be publicly available, in the same manner as drugs that are regulated through FDA. Site-specific production volumes should also be publicly available after a reasonable embargo. In addition, because research on many chemicals is hindered by a lack of authentic standards, samples of any chemical substance produced or imported into the United States of America should be archived in a national repository funded by the chemical industry.
4. To adequately protect the American public and the environment from toxic chemicals, chemicals that were grandfathered-in through TSCA in 1976 need to be re-assessed, as exemplified by more recent flame-retardants now on the market, such as Firemaster 550.
5. TSCA reform in the US should make use of data gathered as part of the E.U.'s REACH program. This information can be then be used in the US to move towards safer and greener chemicals, and spur the innovation of less toxic and persistent compounds.

Dear members of the House Committee on Energy and the Environment, I want to thank you for inviting me to testify on new chemical reviews under TSCA and the role of Confidential Business Information (CBI).

My name is Rainer Lohmann, I am a Professor of Oceanography at the University of Rhode Island. I have spent the last 15 years researching the fate and transport of organic contaminants around the world. My particular focus is on persistent organic pollutants, or POPs. These are compounds which we worry about at the local, regional, national and international scale due to their persistence, their ability to travel long distances, their strong bioaccumulation affecting top predators and lastly their adverse effects in organisms. Some of the worst persistent organic pollutants are well-known, such as DDT, PCBs, chlorinated dioxins and furans.

Right now, I am about to publish a viewpoint article on TSCA reform. Together with my colleagues Dr. Heather Stapleton (Duke University), Ron Hites (Indiana University), we discuss, from the perspective of environmental chemists/engineers/toxicologists, what a new TSCA should adhere to. I will enclose this document in my written testimony, and use excerpts here. My testimony today will focus on chemical review within TSCA, its inventory and the role of CBI within TSCA.

1.) The TSCA inventory

Within TSCA, chemicals are all considered innocent until proven guilty. While this approach is appropriate for US citizens accused of a crime, from my perspective, it is a dangerous approach to use with chemicals in commerce. In fact, any new, or existing chemical should be first

holistically evaluated for its safety in its intended use, and in its life after or outside its intended use. The current platform from which TSCA operates holds the American public hostage to the chemical manufacturers. As you know, currently EPA has to first prove that a chemical has the potential to cause harm before it can be banned. While theoretically this may sound reasonable, in practice this has not been effective. While dozens of chemicals have been "voluntarily" phased out due to public pressure and international regulations, legally only five have been banned through TSCA, and the last ban was in 1980s. A major shortcoming of the TSCA is the lack of information about compounds, their identities, properties and potential toxicity. This is not helped by what seems an excessive use of CBI.

2.) Unknown POPs/PBTs hidden in the TSCA inventory

While we will never know the exact number, there are between hundreds to thousands of compounds included in the current TSCA inventory that have the properties of PBTs (Strempel et al. 2012). In other words, these compounds are most likely persistent, bioaccumulative, and toxic. Scientists have highlighted the most worrisome or 'emerging PBTs' in their 'top 50 compounds' to detect and worry about (Howard and Muir 2010; Howard and Muir 2011) .

Some recent examples include

- perfluorinated compounds used as stain repellents in clothing, carpets and in kitchenware which are now routinely detected in the oceans and top predators from the Arctic to the Antarctic (Benskin et al. 2012) and in the blood of almost every American (Calafat et al. 2007);
- flame retardants used in residential furniture, baby products, automobiles and electronic appliances, such as polybrominated diphenyl ethers, that are now present across the globe,

present in almost all animals and found in more than 97% of the American population (Hites 2004);

- or personal care products such as cyclic methylsiloxanes that are found in the Arctic atmosphere and many organisms even in remote places (Krogseth et al. 2013);

Efforts to fully understand the magnitude of persistent chemicals in the environment are hampered by the lack of basic information about the chemicals' identity, properties, toxicology and production volume (Arnot and Mackay 2008; Brown and Wania 2008; Howard and Muir 2010). If TSCA was meant to protect the American public and the environment from toxic chemicals, it has failed spectacularly.

3.) Confidential business information within TSCA

TSCA does not limit the period in which a chemical can be considered proprietary or a trade secret. New pharmaceuticals are patented for up to 20 years, providing a drug company time to recoup its research investment and make a profit. When the patent expires, other companies can produce generic versions of the drug. This arrangement is a suitable compromise between industry's right to a protected market and the public's right to less-costly drugs.

Within TSCA, the chemical industry should have a limited time during within which the information submitted to the EPA will be considered proprietary. After this time, information should be publicly available, including site-specific production volumes. The public has a right to know what is produced, and where.

In addition, because research on many chemicals is hindered by a lack of authentic standards, samples of any chemical substance produced or imported into the United States of America should be archived in a national repository funded by the chemical industry.

4.) Hidden chemical identities and detectives work.

Some of my colleagues are spending a significant part of their time identifying unknown man-made chemicals in the environment. This task is exacerbated by the secrecy surrounding registered chemicals, particularly in the U.S. The first report on PCBs was an accidental find by a Swedish scientist, Dr. Soren Jensen, looking for DDT in human blood in the 1960s. Sadly, serendipity continues to play a role in detecting chemicals in our households, animals and the environment.

I will use the story of how Dr Stapleton from Duke University first discovered the flame retardant Firemaster 550 in household products and dust etc. It highlights the problems with "grandfathering" in chemicals, and the problems with CBI in general.

Dr Stapleton discovered FM 550 by accident while screening house dust samples for PBDEs (flame retardants that are not produced any longer in the US). She pointed out that she often wonders how long it would have taken her to identify FM 550 if she had not stumbled upon this by accident that day.

Her research on flame retardant exposures demonstrated that FM 550 is a ubiquitous indoor contaminant, and exposure is higher for infants and toddlers relative to adults (Stapleton et al. 2008). In 2011 and again in 2012 she and her group demonstrated that FM 550 is the 2nd most common flame retardant applied to both baby products and residential furniture today (Stapleton et al. 2012). Today, FM 550 is poised to become the #1 flame retardant using in baby products and residential furniture due to the recent withdrawal of yet another flame retardant TDCPP (a suspected carcinogen). In their most recent work, Stapleton and co-workers demonstrated that prenatal exposure to FM 550 in rats resulted in obesity, early puberty, insulin resistance, and

disrupted thyroid hormone signaling (Patisaul et al. 2013). And more importantly, the doses they used in these experiments (that resulted in these adverse effects) were an order of magnitude lower than the level the chemical manufacturer (Chemtura Inc.) indicated was the NOAEL (no observed adverse effect level).

In 2005, EPA issued a consent order requesting that Chemtura conduct more testing on FM 550's health effects. However, this testing was limited, and from my perspective, compromised, by TSCA's inherent flaws regarding chemicals that were "grandfathered-in". FM 550 contains four ingredients, two of which are brominated (a brominated benzoate and brominated phthalate), and both have recently been shown to be increasing in the atmosphere around the Great Lakes (Ma et al. 2012). The other two ingredients in FM 550 are organophosphates, which have been used for decades and were grandfathered into TSCA. Therefore, when the consent order was issued, EPA could only require testing on the two new brominated compounds, and not the mixture in its entirety. This highlights the shortcomings of TSCA, and how it violates common sense. If you market a chemical mixture, you should perform toxicity tests on that mixture, as it will be used, and how people will be exposed to it in the environment. Professor Stapleton's research on FM 550 is the only study to date to examine health effects from the mixture as it is used today. Their data demonstrated that significant effects occur at a much lower dose than what the chemical company declared to be "safe" (Patisaul et al. 2013).

Using a different approach, Dr Michael Milligan from SUNY Fredonia is analyzing fish eggs from the Great Lakes for chemical. He has easily identified around 1000 individual compounds that are likely of man-made origin. Again, part of his problem in positively identifying all

compounds is a lack of information on chemical use, their properties, and a lack of available analytical standards to confirm suspected chemical identities.

5.) Other countries regulation of chemicals

As you are fully aware, the European Union has passed sweeping legislation focused on chemical safety called Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) (Christensen et al. 2011). Whether you disagree or agree with REACH, its intent and procedures, it is happening as we speak.

Global chemical industries adhere to the rules laid out by REACH already. It forces companies to provide significant amounts of data on chemicals' properties and toxicity to the European Chemicals Agency. It also intends to instill a cradle-to-grave perspective for both chemical manufacturers and down-stream users of chemicals. Another key aspect of REACH was that they removed the protection for existing ('grandfathered-in') chemicals, thus leveling the playing field, spurring innovation into newer and safer chemicals (Abelkop et al. 2012).

My hope is that TSCA reform in the US will take advantage of the resoures REACH is generating, such that the information gathered through REACH can be used in the US to move towards safer chemicals with a "greener" design. Due to REACH, we know a lot more about the most persistent, bioaccumulative and toxic chemicals. This treasure trove of data should be harnessed as efficiently as possible, to reduce and remove unsafe chemicals from the market, minimize exposure, and spur the innovation of newer and safer chemicals.

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SCIENCE SHOULD GUIDE TSCA REFORM

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The Toxic Substances Control Act (TSCA) of 1976 tasks the U.S. Environmental Protection Agency (EPA) with managing chemical safety in the United States. TSCA works by a system of pre-manufacture notifications (PMNs), which are submitted to the EPA by industry when a company wants to market a new chemical or an old one for a new use. The notification to the EPA includes information on the chemical's composition and intended use. However, one of the major shortcomings of TSCA is the lack of health testing of new chemicals. If a company has any toxicity data, they are required to submit the data with the PMN, but there are no requirements to collect health data prior to PMN submission. After reviewing the PMN, the EPA then responds with permission to produce or market the chemical, a request for additional data, or with a denial. Certain substances are generally excluded from TSCA, such as foods, drugs, cosmetics, and pesticides.[1]

TSCA has not been as effective as originally hoped; in fact, some refer to it as the Toxic Substances *Conversation* Act in tribute to its slow pace. Reform is needed. Much has changed

since 1976. PCBs, DDT, mirex, and endosulfan are no longer on the market; the Stockholm Convention on persistent organic pollutants (POPs) has come into force; and the European Union has passed sweeping legislation focused on chemical safety called Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).[2]

TSCA reform is underway. Stakeholders in this effort include governmental, industrial, and non-governmental organizations and academic scientists. While many scientists typically avoid the political process, we maintain that the scientific community has valuable expertise and must be at the table as TSCA is rewritten. With scientific input, the U.S. can learn from past mistakes and benefit from decades of research on chemical fate and effects.

What are the key elements to a reformed TSCA?

1. "Innocent until proven guilty" should not apply to chemicals. TSCA is based on the assumption that a chemical is safe until proven harmful. This is a fatal flaw. Numerous studies have suggested that there are hundreds to thousands of chemicals that have the properties of POPs.[3] New legislation needs to turn the proof of chemical safety over to manufacturers. No agency is capable of adequately assessing all chemicals for their safety. It is the manufacturer's responsibility to demonstrate safety of their product, and the EPA's role to critically review these assessments. This is how REACH is designed.[2]

2. "Grandfathering in" of chemicals spells trouble for the future. When TSCA was implemented in 1976, substances that were or had been produced at that time were exempt from the legislation. Obviously, it was in the chemical industry's best interests to have as many of their products or potential products on this list as possible, and as a result, at least 50,000 substances were exempted from regulation. These exemptions formed the initial TSCA

Inventory, and these exemptions must be re-assessed. REACH provides a mechanism for exemptions, but requires industry to justify the need for an exemption.[2]

3. Single-compound replacements are no alternative for structural reform. When polybrominated biphenyls (PBBs) contaminated Michigan in 1977, they were withdrawn from the flame retardant market and replaced by polybrominated diphenyl ethers (PBDEs). When the environmental ubiquity of PBDEs became apparent in 2000, they were withdrawn from the market and replaced by polybrominated benzoate and phthalate esters.[4] This stepwise approach is not sustainable in the long term, and indeed, the flame retardant industry is shifting to products that save lives but do not leak into the environment.

4. There are many biological and ecological endpoints to consider. Toxicology is a difficult science. What toxic effects should one consider? How does one evaluate long-term chronic exposures? How can particularly sensitive populations (e.g. young and elderly) be protected? Can biochemical, proteomic, or genomic experiments (vs. whole animal experiments) be used for regulatory purposes? Any changes to TSCA should recognize these challenges and be less proscriptive and more holistic.

5. Mixtures of chemicals may have greater environmental impacts than the chemicals alone. Traditional legislation has focused on a single chemical at a time. Yet environment exposures occur in complex mixtures. Key studies have shown that a cocktail of many individual compounds below their respective no observed effect levels can still result in significant adverse effects.[5] While TSCA is currently designed to evaluate chemicals independently, many chemical manufacturers sell their products as mixtures; therefore, evaluations should be conducted not only on individual chemicals, but also on the mixture as marketed. It is also important to assess the toxicity of impurities in mixtures.

6. Restrictions on access to proprietary information submitted to the EPA by industry should not be permanent. TSCA does not limit the period in which a chemical can be considered proprietary or a trade secret. In the pharmaceutical arena, new drugs are patented for up to 20 years, providing a drug company time to recoup its research investment and make a profit. When the patent expires, other companies can produce generic versions of the drug. This arrangement is a suitable compromise between industry's right to a protected market and the public's right to less-costly drugs. Within TSCA, the chemical industry should have a limited time during which the information submitted to the EPA will be considered proprietary. After this time, information should be publicly available. Site-specific production volumes should also be publicly available after a reasonable embargo. In addition, because research on many chemicals is hindered by a lack of authentic standards, samples of any chemical substance produced or imported into the United States should be archived in a national repository funded by the chemical industry.

7. Scientists are willing to help. Many of us have dedicated our professional lives to better understanding chemicals' environmental concentrations, properties, transport, fates, and effects. Can we afford to just stand-by? If TSCA is not reformed, the unrestricted production, use, and release of unsafe chemicals could continue, and with it the on-going exposure of the American public to a complex mixture of these chemicals. We have an obligation to make our voices heard and to promote proven scientific principles as a basis for TSCA reform. We can do this through our scientific organizations and via our representatives in Congress.

Acknowledgements

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