The Center for International Environmental Law

Representative Jon Shimkus, Chairman
Representative Paul Tonko, Ranking Member
Subcommittee on Environment and Economy, Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

RE: Submission for Subcommittee hearing on "Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation"

July 11, 2013

Dear Chairman Shimkus, Ranking Member Tonko, and Members of the Subcommittee:

The Center for International Environmental Law (CIEL) appreciates the opportunity to submit comments regarding today's hearing on the "Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation" under the 1976 U.S. Toxic Substances Control Act (TSCA) by the House Subcommittee on Environment and the Economy. Established in 1989 and based in Washington D.C., CIEL is a nonprofit organization that uses the power of the law to protect the environment, promote human rights and ensure a just and sustainable society.

CIEL examined trends in chemicals regulation and patent filings to evaluate the impact of stronger rules for hazardous chemicals on the innovation of new chemicals products. Looking at examples from within the United States and abroad, our study *Driving Innovation*[1] found that stricter regulation of hazardous chemicals can not only drive innovation, but also create a safer marketplace. As overwhelming evidence continues to grow about the financial costs of inaction on the hazardous cocktail of substances to which Americans are exposed daily, the need to direct our effort on innovation toward safer chemicals is particularly salient.

[1] CIEL, *Driving Innovation: How stronger laws help bring safer chemicals to market* (2013), available at: http://ciel.org/Publications/Innovation_Chemical_Feb2013.pdf

While certain chemical manufacturers publicly insist that "there is no evidence that stricter chemical laws promote innovation,"[2] our study found clear and convincing evidence that the prospect of stricter rules on toxic chemicals sparked the invention, development, and adoption of alternatives. For example, in response to stricter rules to protect people and the environment from phthalates, a class of chemicals with hormone (endocrine) disrupting properties, our study of international patent filings shows acceleration in the invention of alternative chemicals and products. Spikes in the patenting of phthalate-alternatives clearly correlate with the timing of new rules to protect people and wildlife from phthalates. As the stringency of measures increased, so too did the number of inventions disclosed in patent filings by the chemical industry. Innovation hinges on the adoption of inventions into the market. Our case studies highlight how stricter rules for hazardous chemicals can accelerate this process--creating incentives that help to pull inventions into the market, and turn invention into innovation. However, barriers exist that prevent the entry of safer alternatives. Overcoming the inertia of entrenched toxic chemicals typically requires the exercise of governmental regulatory authority. Our findings show that stricter rules enable safer chemicals to overcome currently existing barriers to entry, such as economies of scale, the externalization of costs, and the lack of information about chemicals and products on the market today.

The findings from our study offer important insights into the two principle innovation-related issues before the Subcommittee today: Pre-manufacture and Significant New Use Notices under TSCA section 5, and the protection of confidential information under TSCA section 14.

Section 5 of TSCA, Pre -manufacture Notification for New Chemicals or Uses.

History is replete with examples of regrettable substitution, where a hazardous chemical is restricted, but then replaced with a different hazardous chemical. The experience of transitioning from one hazardous flame-retardant chemical to another illustrates not only the dangerous presumption of safety about chemicals on the market in the 1970s, but also the weakness of programs such as those under Section 5 of TSCA to evaluate recently developed chemicals for their hazardous properties.

We found examples of alternative chemicals with a high-degree of structural similarity to the hazardous chemicals they replaced, with inadequate information about the alternative's potentially hazardous properties. For example, new chemical alternatives to hazardous flame retardants—chemicals which are being phased-out under a global treaty for some of the world's most dangerous toxins—entered the market with a startling lack of toxicological information despite structural similarity to known hazardous chemicals. Given their structural similarity, a heightened level of scrutiny is prudent before use of such chemicals in consumer products; however, under existing rules, additional information took years to be requested and provided.

[2] Pat Rizzuto, *Law Center Says Strict Chemical Controls Foster Innovation, Markets, Protect People*, Chemical Regulation Reporter, 37 CRR 194 (Bloomberg BNA, Feb. 18, 2013), available at: http://ciel.org/Chem/Innovation_BNA_18Feb2013.html

In order to increase the likelihood that safer alternatives will be pulled into the market, chemical laws need to clearly identify hazardous properties that are not acceptable in society, generate information about these properties in all chemicals, and require their substitution with safer alternatives in a systematic way. Under Section 5 of TSCA, new chemicals are not required to be *likely* to meet the safety standard. Moreover, manufactures are not required to generate and provide to regulators *any* health and safety information. Stricter rules for new chemicals can enable a transition to safer alternatives.

Section 14 of TSCA, Protection of Confidential Information

Inventors need access to information about chemical hazards and exposures to develop safer solutions. Consumers and downstream users need access to information about chemicals in products to enable them to choose safer products, thereby incentivizing innovation toward safer alternatives. And regulators need access to hazard and exposure information to restrict the use of hazardous chemicals, enabling the entry of safer alternatives.

Of particular concern to businesses is the need to protect confidential business information (CBI). However, the abuse of CBI privileges under TSCA is well documented,[3] and this represents a serious barrier to the identification of hazardous chemicals and the development and entry of safer alternatives. Recent experiences show that the inability to access information can impede the development and adoption of safer alternatives. Incomplete information on potential alternatives enables "regrettable substitution," i.e. the transition from one hazardous chemical to a different hazardous chemical, instead of safer alternatives.

While respecting the desire to protect legitimate CBI is a means of encouraging businesses to continue to innovate, policy makers around the world have long recognized the potential for the disclosure of information to promote additional innovation. Patents are based on this principle. Recent changes to European laws that increase access to information on substances of very high concern is "the driver for change at the present,"[4] according to a 2012 review of the impact of these stronger laws on innovation. For information to accelerate and steer innovation in a safer direction—and ensure the integrity, efficiency, effectiveness, and accountability of governments, institutions, and industry—health and safety information must be generated and access must be provided to that information.

Although TSCA already recognizes that health and safety information should never be CBI, it still has farther to go in properly balancing these interests. Despite limits to the type of information that may be claimed as CBI, regulators do not always require justification of claims

[3] Government Accountability Office (GAO), *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458 (Washington, D.C.: June13, 2005).
[4] Centre for Strategy & Evaluation Services, *Final Report, Interim Evaluation: Impact of the REACH Regulation on the innovativeness of the EU Chemical Industry*, (hereinafter "REACH Innovation Report") pp. xii (emphasis added) (June 14, 2012), available at:
http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/innovation-final-report_en.pdf

of confidentiality or re-justification of claims after a period of time. A further problem is the practice of allowing the identity of chemicals that are the subject of health and safety studies to be masked as CBI, impeding the identification of chemicals of concern. Unlike patents, which generally expire after twenty years, CBI can be kept confidential in perpetuity. The health and environmental risks of this approach are compounded when important information is inappropriately claimed to be CBI.

Conclusion and Recommendations:

In sum, progressively stricter laws spur the innovation of safer alternatives and can pull safer alternatives into the market, enabling them to overcome barriers to entry. But, changes to TSCA sections 5 and 14 are necessary to ensure that alternatives do not also have intrinsic hazards to better ensure that innovation creates a safer marketplace. To this end, CIEL respectfully offers the following recommendations to strengthen the regulatory framework within and beyond TSCA to accelerate innovation towards safer chemicals:

1. **Ensure the burden of proving chemical safety falls on chemical manufacturers for new and existing chemicals**: Requiring that chemical manufacturers generate information about the intrinsic hazards of both existing as well as new chemicals levels the playing field for safer chemicals and enables a more meaningful assessment of alternatives. This information enables regulators to remove entrenched chemicals of concern, empowers downstream users to deselect hazardous chemicals from their supply chain, and equips chemical manufacturers to innovate towards safer alternatives. Although recent progress has been made by countries around the world in placing the burden of proving chemical safety on chemical manufacturers, greater measures are needed in the United States.

2. **Promote access to information**: Inventors need access to information about chemical hazards and exposures to develop safer solutions. Regulators need access to hazard and exposure information to restrict the use of hazardous chemicals, enabling the entry of safer alternatives. Consumers and downstream users need access to information about chemicals in products throughout the supply chain to enable them to choose safer products, thereby incentivizing innovation toward safer alternatives. Policy makers should ensure that health and safety information is generated and made available to consumers, businesses, and regulators, including information on and awareness of products containing hazardous chemicals. Claims of confidentiality should be justified, periodically re-justified, and never granted for health and safety information to enable the development of safer alternatives.

3. **Phase-out chemicals with certain intrinsic hazards**: U.S. EPA must possess—and exercise—the power to remove hazardous chemicals from the market based on their intrinsic hazards.

4. **Recognize endocrine disruption as an intrinsic hazard that cannot be soundly managed**: Endocrine disruption is an intrinsic hazard of certain chemicals, linked to a myriad of

adverse effects that have been on the rise over the past several decades. As there is no safe level of exposure to endocrine disrupting chemicals (EDCs), they should be recognized as a distinct category of chemicals that needs to be phased out globally, similar to other chemicals with intrinsically hazardous properties.

5. **Internalize the costs of hazardous chemicals**: Not only would this lead downstream users to shift to alternatives with lower costs, it would also incentivize chemical manufacturers to invest in the research and development of safer alternatives.

6. **Craft stronger international laws to ensure a level-playing field for U.S. businesses**: Only a narrow sliver of chemicals of concern on the market are covered under legally-binding global treaties throughout their lifecycle. A broader international regime designed to cover a wider range of hazardous chemicals and chemical-related risks could help to create a level-playing field for American businesses operating in a globalized world.

Respectfully submitted,

Baskut Tuncak
Staff Attorney,
Center for International Environmental Law (CIEL)

Enclosure: CIEL, *Driving Innovation: How stronger laws help bring safer chemicals to market*, (Executive Summary, 2013)

1350 Connecticut Avenue N.W. Suite 1100 • Washington D.C. 20036-1739

Phone: 202-785-8700 • Fax: 202-785-8701 • Email: info@ciel.org • Internet: http://www.ciel.org

15 rue des Savoises, 1205 Geneva, Switzerland

Phone: 41-22-789-0500 • Fax: 41-22-789-0739 • Email: geneva@ciel.org • Internet: http://www.ciel.org