

STATEMENT OF CARROLL MUFFETT PRESIDENT AND CEO CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW (CIEL) ON BEHALF OF CIEL, FRIENDS OF THE EARTH AND SIERRA CLUB

BEFORE THE U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON ENERGY AND COMMERCE SUB-COMMITTEE ON COMMERCE, MANUFACTURING AND TRADE

HEARING ON
THE U.S. – E.U. FREE TRADE AGREEMENT: TIPPING OVER THE REGULATORY
BARRIERS

JULY 24, 2013

Thank you, Chairman Terry and Ranking Member Schakowsky for the opportunity to appear before this subcommittee today.

I am Carroll Muffett, President and CEO of the Center for International Environmental Law (CIEL), 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 works closely with a broad range of stakeholders in the United States, Europe and around the world on a diverse range of issues in environmental law and policy, including climate change, toxic chemicals, natural resource conservation and extraction, international financial institutions, human rights, biodiversity and international trade. CIEL offers this testimony on its own behalf and on behalf of Friends of the Earth and the Sierra Club

I. Summary of Key Messages

I would like to begin by briefly summarizing the key messages of my testimony.

The current system for regulation of chemicals is wholly inadequate to meet the challenge posed by the modern chemicals economy. Cancer rates have increased. The amounts of chemicals in our bodies have increased. Absent greater regulatory action, they will continue to increase. This is a international public health problem that *remains unsolved*. Public health is one of the core responsibilities of a government to its citizens, and it is one that is currently not being adequately addressed with regard to chemicals. The scarcity of detailed information on TTIP, particularly from the United States, make any assessment of its eventual impact inherently speculative.

While TTIP *could* offer an opportunity to elevate regulations in the U.S. and the EU, experience with other trade agreements, together with the explicit intention of reducing regulatory barriers to

trade, make it far more likely that TTIP will hinder important public health and safety goals related to chemicals. To reduce this likelihood, TTIP:

- must ensure that both the EU and U.S. retain the right to determine their own levels of
 health protection from toxic chemicals, and develop measures to reduce exposure to
 hazardous chemicals as they see fit;
- should not include provisions for mutual recognition for the chemicals sector and other sensitive sectors;
- must not include provisions for investor-state dispute resolution;
- should not impede the rights of states and local governments, or of governments outside
 the United States and E.U., to adopt new initiatives on toxic chemicals and other
 environmental issues, including their right to choose higher levels of protection for their
 citizens;
- should not impede regulatory efforts to address emerging issues of concern, such as nanotechnologies, endocrine disrupting chemicals or hydraulic fracturing;
- must be negotiated in an open, transparent and participatory manner that safeguards the universal and fundamental public interest in the outcomes of the negotiations.

II. Introduction

For over twenty years, CIEL has advocated for a positive trade agenda, where increased market access does not undermine environmental protections or human rights. Until 2011, CIEL served on the Trade and Environment Policy Advisory Committee (TEPAC), a Tier 2 Policy Advisory Committee. In addition, a senior attorney from CIEL served as the first public interest representative on a Tier 3 Technical Advisory Committee for the chemical and allied industries. CIEL has previously testified before the Committee on Ways and Means on trade matters and

has testified before this Subcommittee with regard to prioritizing chemicals for safety determination. In recent months, CIEL has published two major reports documenting the often positive relationship between stronger regulation and innovation in chemicals markets and identifying critical gaps in the global framework for chemical safety.

I have been invited to address the environmental implications of removing perceived regulatory barriers to trade between the United States and the European Union through the Transatlantic Trade and Investment Partnership (TTIP). My testimony will focus on the potential impact of the negotiations on regulations intended to protect people and the environment from toxic chemicals.

This testimony, and the conclusions and inferences drawn here, are necessarily preliminary in nature and, to some extent, speculative. This owes not only to the early stage of these negotiations, but to the consistent and regrettable practice of the United States government in limiting public access to information in all of its trade negotiations. In consequence, my conclusions here are drawn from thee limited information that is publicly available, key pieces of which are months out of date or at high levels of generality. They draw heavily on materials released by the European Union on its own positions because comparable materials reflecting the initial positions of the United States have not been shared with the general public.

We have chosen the chemicals sector because of the significance of recent shifts in outdated chemical policies in the European Union (EU), and the potential benefits of implementing related laws in the EU on the health and environment of people around the world, including those in the U.S.

Both the UN Environment Program (UNEP) and Organisation for Economic Cooperation and Development (OECD) project that chemical production use and therefore disposal will continue to increase significantly over the next several decades. On both sides of the Atlantic, the public is concerned about the long-term effects of chemicals on health, including increasing incidence of asthma, autism, birth defects, infertility, Alzheimer's and Parkinson's diseases, and certain types of cancer. These problems are especially troubling in light of the growing evidence that industrial chemicals are increasingly present in our bodies and in the environment. In seventeen years, we have seen a 20 percent increase in the incidence of childhood cancer – an increase that cannot be explained by genetics or lifestyle choices. Recent polls show over 70 percent of Americans, throughout the political spectrum support stronger rules for toxic chemicals.

Since the formation of the World Trade Organization (WTO) in 1995, U.S. and European officials have accelerated transatlantic efforts to develop and apply three significant trade promotion devices: harmonization, equivalence, and mutual recognition. Their goal has been to reduce what industry considers non-tariff (or technical) barriers to trade posed by regulatory requirements. The three trade promotion mechanisms are closely related but are not interchangeable. With respect to TTIP, chemical manufacturers, downstream users of chemicals and related trade associations call for the elimination of non-tariff barriers to trade through "enhanced regulatory coherence" or similar terminology.

As implied by the Final Report of the High Level Working Group on Jobs and Growth and explicitly recognized in the EU's position papers, the "[e]limination, reduction and prevention of

_

¹ U.S. EPA, *America's Children and the Environment, Third Edition* (last accessed July 23, 2013), available at: http://www.epa.gov/envirohealth/children/health/childhood_cancer.html (citing data from National Cancer Institute, Surveillance, Epidemiology and End Results Program)

unnecessary regulatory barriers are expected to provide the biggest benefit of the TTIP."²
Industry submissions reflect a similar expectation that TTIP will serve primarily as an opportunity reduce non-tariff barriers to trade. Provisions on harmonization, equivalence, mutual recognition and other provisions that may be included in TTIP could weaken standards for human health and the environment in both the EU and U.S., preempt state laws in the United States, restrain the continued development of REACH in the European Union, and influence the development of chemical laws outside the U.S. and EU, in particular the BRIICS countries (Brazil, Russia, India, Indonesia, China, South Africa). I will focus on five specific issues: (1) harmonization (2) mutual recognition; (3) investor state dispute settlement; (4) preemption of laws at the state-level in the United States and the national-level by EU member countries; and (5) influencing the development of laws outside the U.S. and EU.

III. Harmonization

Harmonization takes two or more differing standards or procedures and converts them into a single, uniform standard. While TTIP *could* offer an opportunity to elevate regulations in the U.S. and the EU, the harmonization of regulatory standards to the "lowest-common denominator" has often been the result of recent U.S. trade agreements, decreasing the level of protection afforded to the public in favor of private interests. ³ Other agreements, such as the North American Free Trade Agreement (NAFTA), failed to harmonize standards between

_

² EU-US Transatlantic Trade and Investment Partnership: Trade Cross-cutting disciplines and Institutional provisions--Initial EU position paper, EC (July 16, 2013) [hereinafter Trade Cross-cutting disciplines], available at http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151622.pdf.

³ For example, although the U.S.-Korea Free Trade Agreement has provisions intended to prevent the two countries from easing environmental standards in order for firms on their territory to gain a competitive trade advantage, U.S. automakers will be considered in compliance with new South Korean fuel economy or greenhouse gas emissions standards if they meet a target level that is 19 % more lenient than the relevant target level provided in the regulation that would otherwise be applicable to that manufacturer, WILLIAM H. COOPER ET AL, CONG. RESEARCH SERV., RL34330, THE U.S.-SOUTH KOREA FREE TRADE AGREEMENT (KORUS FTA): PROVISIONS AND IMPLICATIONS (2013), available at http://www.fas.org/sgp/crs/row/RL34330.pdf.

Mexico, the U.S. and Canada, which has resulted in the transfer of dangerous and environmentally unsound industrial activity to Mexico.⁴ This poses a serious threat to the environment, working families, and communities. It is therefore imperative not only that regulations are harmonized upward, but also that any convergence of regulations serves as a regulatory floor that allows governments the flexibility to develop more ambitious environmental and public interest policies in the future.

In the case of certain regulations in the EU and U.S., it is difficult to envision any degree of harmonization. Regulations for chemicals management offer one such example. EU and U.S. approaches diverge significantly, with the European Commission acknowledging in documents prepared for TTIP that "US requirements [for chemicals] are less strict" and that, in the view of the EU, "neither full harmonisation nor mutual recognition seem feasible on the basis of the existing framework legislations in the US and EU."

A fundamental difference between U.S. and EU approaches to chemicals management is how the safety of chemicals is assessed. For several decades, the EU had laws in place for industrial chemicals that were similar to the 1976 U.S. Toxic Substances Control Act (TSCA), employing a risk-based approach. However, since the adoption of REACH in 2006, the EU has taken hazard-based approach to industrial chemicals, a substantial but necessary step towards reducing the use of and exposure to hazardous chemicals.

⁴ For example, a disturbing trend involving the export of Spent Lead-Acid Batteries (SLABs) for recycling has developed over the last several years. While the U.S. battery recycling industry has increased safety standards and lowered emissions, developing countries, like Mexico, are not keeping pace. While the U.S. has strict regulations governing lead emissions and employee blood lead exposure, no similar comparable regulatory regime can be found in Mexico. The Blacksmith Institute estimates that more than 12 million people are adversely affected by lead contamination from improper processing of SLABs. Since NAFTA, an increasing number of SLABs are exported to Mexico from U.S. battery dealers and manufacturers. In 2012, 754 million pounds of used batteries were exported to Mexico, *see* SLAB WATCHDOG, http://www.slabwatchdog.com/problem/slabs-2/ (last visited July 23, 2013).

⁵ Note for the Attention of the Trade Policy Committee on the Transatlantic Trade and Investment Partnership, Annex 2--Initial Position Paper: Chemicals in TTIP, June 20, 2013, EC Trade Policy Committee (June 21, 2013) [hereinafter Chemicals in TTIP].

The EU's REACH Regulation for industrial chemicals is heralded as a necessary paradigm shift away from the dangerous presumption of safety that applied to over 60,000 chemicals in the United States and over 100,000 chemicals in the European Union in the 1970s – an assumption that has repeatedly been shown to be false. REACH clearly identifies hazardous properties that are not acceptable in society, generates information about these properties in chemicals produced over one ton per year, and encourages the substitution of hazardous chemicals with safer alternatives in a systematic way.

Under REACH, hazardous chemicals that are not acceptable include those that: are carcinogens, mutagens, or toxic to reproduction; exhibit a certain degrees of persistence in the environment and the ability to accumulate in living organisms; or otherwise rise to an equivalent level of concern, such as endocrine or hormone disrupting chemicals. Categorized as substances of very high concern (SVHCs) under REACH, these chemicals are subject to certain requirements to protect people and the environment, and help downstream users of these chemicals transition to safer alternatives. According to the European Commission's mandated assessment of the impact of REACH on innovation, this hazard-based approach to listing of substances of very high concern in the candidate list is "the driver for change at the present." In other words, the hazard-based approach in REACH is driving innovation away from the status quo mix of hazardous chemicals on the market, and is not an impediment to innovation.

By contrast, the risk-based approach to chemicals management applied by the United States has not been significantly updated since TSCA was adopted more than 35 years ago, notwithstanding tremendous and fundamental changes in our understanding of chemical hazards over the ensuing

⁶ CENTRE FOR STRATEGY & EVALUATION SERVICES, FINAL REPORT, INTERIM EVALUATION: IMPACT OF THE REACH REGULATION ON THE INNOVATIVENESS OF THE EU CHEMICAL INDUSTRY xii (June 14, 2012) (emphasis added), [hereinafter REACH Innovation Report], *available at* http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/innovation-final-report en.pdf.

decades.⁷ This risk-based approach requires projections for exposure level and other socioeconomic considerations to be taken into account before chemicals are restricted. Although in
theory this approach could enable a scientific approach to assessing the risk associated with a
substance, the theory is not borne out in practice. It demands a complete risk assessment before
any regulatory action is taken, requiring a reasonably complete set of data on hazard and
exposure, as well as significant resources for its analysis from public authorities, rather than
placing the burden of proving safety on the regulated industry. As one commentator observed,
"The balancing of risks in the face of a very high hurdle of uncertainty under TSCA leaves EPA
almost paralyzed to take action to regulate toxic substances." Over 35 years of experience from
the U.S. and around the world has proven that this approach is unable to drive innovation away
from hazardous chemicals and enable the entry of safer alternatives.

Most existing chemicals still lack toxicity data relevant to hazard assessment. Regarding exposure, data also are lacking on production volume and use, which are critical for determining the potential for human and environmental exposure and for risk assessments and prioritization. Human bio-monitoring data exists for only a hundred or so of the tens of thousands of industrial chemicals and pesticides that are regularly used and released into the environment. Moreover,

⁷ See, e.g., LINDA-JO SCHIEROW, CONG. RESEARCH SERV., RL34118, THE TOXIC SUBSTANCES CONTROL ACT (TSCA): IMPLEMENTATION AND NEW CHALLENGES 25 (2008) (noting that TSCA was adopted only four years after the first textbook on toxicology was published and observing that "TSCA reflects the concerns of the early days of toxicology, and the knowledge and methods of that first toxicology book."); see id. at 36 ("Even if one concludes that TSCA has performed successfully in the past, it may be reasonable to question the adequacy of a 1976 chemical law in the light of thirty years of scientific and technological advances."); Compare LINDA-JO SCHIEROW, CONG. RESEARCH SERV., RS22673, CHEMICAL REGULATION IN THE EUROPEAN UNION: REGISTRATION, EVALUATION AND AUTHORIZATION OF CHEMICALS (2012).

⁸ Robert B, Reform of the Toxic Substances Control Act: Achieving balance in the regulation of toxic substances, 6 ENVTL. LAW, 99, 119 (1999) (quoted in CRS Report RL34118, *supra* note 7).

⁹ The EU abandoned this approach because it concluded that chemicals were not properly controlled; there was a general lack of knowledge about the properties and the uses of existing substances; and the risk assessment process was slow and resource-intensive, which did not allow the system to work efficiently and effectively, *see* THE ONLY PLANET GUIDE TO THE SECRETS OF CHEMICALS POLICY IN THE EU: REACH (2004).

¹⁰ CRS Report RL34118, *supra* note 7, at 17.

with respect to new chemicals, roughly two-thirds of submissions for approval to manufacture the new chemical do not include test data on chemical properties, and almost 85% of submissions provide no data on health effects.

A fundamental problem with the risk-based approach is that it disregards that there will always be data gaps in the scientific part of the assessment and assumptions must be made. These assumptions, from the degree of exposure to the potential for a chemical to accumulate in living organisms, are often not accurate.

Nor would the proposed, but widely criticized, Chemical Safety Improvement Act close this gap between US and EU regulatory approaches in the absence of significant improvements. As the EU's initial position paper on Chemicals highlights, "the draft legislation does not foresee any general registration obligation for substances as a condition for their marketing (a fundamental requirement under REACH), nor elements comparable to authorisation."

Recently, the European Union has emerged as a global leader in acknowledging and beginning to address urgent issues in chemicals management, such as endocrine disrupting chemicals, nanotechnologies, and the risks presented by chemical mixtures. Endocrine or hormone 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 need to be phased out globally. Nanomaterials have unique physical and chemical properties that make them distict from traditional substances. They are increasingly used in a wide-range of products, but assessment methods are still not attuned to the properties of nanomaterials and precaution is warranted. Mixture toxicity recognizes that we are exposed to

¹¹ Chemicals in TTIP. *supra* note 5.

hundreds of hazardous chemicals daily. Adverse effects have been observed by mixtures of chemicals at levels where the individual chemical is not expected to result in any adverse effects, i.e. the additive, synergistic or 'cocktail' effect of chemical mixtures.

Submissions by the chemical industry highlight these as "current regulatory issues with potential for significant impact on trade." Regulations for these issue areas are still in development and generally not yet in place. The European Commission notes that "where neither side has regulations in place, the making of common – or at any rate coherent – technical regulations may be considered by the Parties." TTIP should seek to address market access issues and to facilitate the resolution of differences without prejudice to the right of the parties to adopt and enforce measures necessary to pursue legitimate public policy goals such as public health, safety and protection of the environment. Initial documents and position papers by the European Commission show varying emphasis to this important flexibility, with greater commitment in some subject areas (SPS and financial regulation) than in the case of technical or non-tariff barriers to trade.¹³

For the past 30 years the OECD has been working to harmonize chemical safety tools and policies across Asia, Europe and North America. Considerable steps and savings for governments and industry have been realized under this process, in which 30 OECD members and several developing countries are participating. Although experts have legitimate criticisms of OECD activities on chemicals, given the rapid expansion of the chemical industry outside the U.S. and EU, such as Asia and Latin America, harmonization discussions should take place in broader multilateral fora, not in the narrow confines of bi-lateral discussions.

. .

 $^{^{\}rm 12}$ American Chemistry Council, ACC submission to USTR, May 10 2013.

¹³ Compare, e.g., EC position papers on SPS (strong language) and TBT (weak chapters of TTIP).

One of five regulatory components of TTIP is the creation of a framework for future regulatory cooperation, including an institutional basis. Position papers by the European Commission suggest the creation of sectoral regulatory cooperation working groups chaired by the competent regulatory authorities, which would in turn report to a regulatory cooperation council or committee. The proposals outline substantial bi-lateral consultation provisions. ¹⁴ In addition, position papers also point to the increased use of voluntary instruments to achieve regulatory objectives. ¹⁵ Together, these elements have the significant potential to delay or dilute the creation of adequate rules to protect human health or the environment.

Given both the substantial differences in approaches between the EU and U.S. and experience with efforts to reform TSCA in the United States, the likelihood of harmonization, 'scientific cooperation,' or 'regulatory coherence,' resulting in a "highest-common denominator" outcome to chemicals management is very unlikely. EU trade negotiators state that they have no intention of lowering EU standards for protecting people and the environment from chemicals under TTIP, and rightfully so. The U.S. should use TTIP as an opportunity to better protect Americans from toxic chemicals, not private interests from the cost of regulations designed to protect people and the environment. At the very least, TTIP should ensure that both the EU and U.S. retain the right to determine their own levels of health protection from toxic chemicals, and develop measures to reduce exposure to hazardous chemicals as they see fit.

IV. Mutual Recognition

A second trade promoting measure is mutual recognition. The EU and the United States have been developing mutual recognition as a trade policy tool over the course of the last decade as

¹⁴ Trade Cross-cutting disciplines, supra note 2.

¹⁵ EU-US Transatlantic Trade and Investment Partnership: Technical Barriers to Trade, EC (July 2013) [hereinafter TBT position paper], *available at* http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc 151627.pdf.

part of their international trade liberalization efforts. Mutual recognition is an agreement between countries to recognize and accept the results of assessments performed by assessment bodies of countries that are parties to the agreement. While the spurported objective of mutual recognition measures is to reduce perceived regulatory barriers to trade, they also have considerable potential to reduce existing levels of national health, safety, and environmental protection.

Supporters of mutual recognition provisions expect them to result in reduced costs and increased market access for industry, as well as freeing up scarce regulatory resources. Consumers are supposed to see these cost savings passed on to them in addition to seeing a wider variety of safer goods appearing earlier in the marketplace. However, it remains to be seen whether these benefits actually do accrue to consumers.

The potential drawbacks of mutual recognition provisions include the following: (1) the transfer of regulatory authority and duties from national regulatory agencies to foreign entities who may operate under different conflict of interest standards and rules of transparency and liability; (2) the privatization of public functions; (3) a loss of domestic regulatory control in crucial public health and safety matters; (4) reduced levels of public participation in regulatory decision making; (5) increased opportunities for regulatory evasion by industry; and (6) reductions in the levels of health, safety, and environmental protection. ¹⁶

The European Commission notes that the "1998 Mutual Recognition Agreement has been successful only in two [of six] areas: telecommunications, and electromagnetic compatibility." The European Commission states that it is not proposed to consider extending the 1998 Mutual

1.

¹⁶ TRANS ATLANTIC CONSUMER DIALOGUE, TACD BRIEFING PAPER ON MUTUAL RECOGNITION AGREEMENTS (March 2001), available at <a href="http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid="http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid="http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid="http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid="http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid="http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid=."http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid=."http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid=."http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid=."http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid=."http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid=."http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid=."http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid=."http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid=."http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid=."http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid=."http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid=."http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid=."http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid=."http://tacd.org/index2.php?option=com_docman&task=doc_view&gid=102&Itemid=."http://tacd.org/index2.php."http://tacd.org/index2.php.

Recognition Agreement "in its present form" to new areas, which does not entirely foreclose the possibility of extending it to other areas. 18

The potential dangers of mutual recognition provisions are well illustrated by their possible application to the chemical regulation. Laws are developing and being implemented in the EU to minimize the use of hazardous substances and encourage their safe substitution. The 2001 'White Paper' by the European Commission estimated that around 1,400 Substances of Very High Concern will be banned in Europe unless an authorisation of a specific use is granted when REACH was implemented. Although slower than expected, progress towards this ambitious but necessary goal is being made. Today, 144 substances are categorized as being eligible for the Authorization procedure and listed under the Candidate List. 22 substances are already scheduled to be phased-out except for certain authorized uses, as early as August of 2014. In addition, another 24 substances are undergoing or are proposed to be subject to REACH's Restrictions process, including the use of bisphenol A or BPA in receipts and other uses of thermal paper.

By contrast, TSCA has only regulated the use of only *six* existing industrial chemicals under TSCA since 1976, from a universe of over 60,000 existing chemicals. U.S. EPA has been unable to use its authority under TSCA to restrict the use of certain chemicals, including numerous chemicals that 179 countries have agreed to phase-out under a global treaty that restricts the use of some of the world's most dangerous industrial chemicals and pesticides.

The regulation of chemicals in cosmetics offers another illuminating example of how little overlap there is between chemicals restricted from certain uses in the EU versus the U.S. The

¹⁸ *Id*.

EU Cosmetics Directive (76/768/EEC) was revised in January 2003 to ban 1,328 chemicals from cosmetics; the U.S. FDA has banned or restricted only eleven. ¹⁹ More recent improvements in the EU include the explicit authorization of colorants, preservatives and UV-filters, including those that are nanomaterials. In addition to giving the Commission the power to require a full safety assessment of nanomaterials used in cosmetics when there is a reason for concern, nanomaterials must be specifically identified in the list of ingredients in cosmetics with the word 'nano' in brackets following the name of the substance.

Some have commented that thirteen chemicals overlap between the EU's candidate list and the U.S. EPA's work plan on existing chemicals and implied that this points to the possibility of convergence around prioritization of hazardous chemicals for regulatory action. It is important to bear in mind, however, that these thirteen substances are drawn from a much larger list of 144 Substances of Very High Concern listed today on the candidate list and 83 chemicals included in EPA's workplan, and possibly over 1,400 in the coming years. ²⁰ In reality, however, EPA's work plans have not produced legally-binding obligations on any chemical included, and thus the number of chemicals that overlap would be far fewer. The chemical industry is lobbying to weaken the candidate list to "better accommodate business needs." ²¹

Mutual recognition in the chemical sector and other sensitive sectors involving public health, safety or the environment is wholly inappropriate. For chemicals, mutual recognition provisions would essentially erase the measures for chemicals that that are restricted in only one jurisdiction. Procter and Gamble states that mutual recognition would "allow[] for the

.

¹⁹ Campaign for Safe Cosmetics, *European Laws*, CAMPAIGN FOR SAFE COSMETICS, http://safecosmetics.org/article.php?id=346%E2%80%8E (last visited July 21, 2013),

²⁰ TSCA Work Plan Chemicals, EPA, http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html (last visited July 23, 2013).

²¹ BUSINESS EUROPE, EU LEGISLATIVE BURDENS ON SMES (Dec. 20, 2012), *available at* http://www.businesseurope.eu/content/default.asp?PageID=568&DocID=31123.

production, sale and use of chemicals that are lawful in one continent to also be lawful in the other."²²

Many chemicals are or will be subject to be significant restrictions in the European Union, but are not subject to similar legally binding measures in the United States. These include: certain phthalates, for uses beyond toys and children's products such as plastics, medical devices and cosmetics, which are linked to reproductive disorders, including genital malformations and decreased sperm levels; hexabromocyclododecane (HBCD), which 179 countries have agreed to phase-out under the Stockholm Convention on Persistent Organic Pollutants, because of its ability diffuse around the world, accumulate in living organisms and evidence of serious adverse effects in animals; and 1,4 dioxane, classified by some entities as a known carcinogen, and prohibited in personal care products. These and other future protective measures are at risk of delay or even elimination with mutual recognition.

Such provisions would require the EU and U.S.to both decide that a chemical warrants restriction in order to protect people in one or both jurisdictions. The continued population of the Candidate List could be delayed, to the benefit of chemical manufacturers with a vested interest retaining the status quo mix of chemicals on the market. The EU has expressed its intention to identify and assess no less than 500 substances of very high concern for substitution by 2020. Such provisions could subject European citizens to the inability of U.S. regulators to take meaningful steps towards chemical safety under a deeply flawed TSCA.Nor are the risks and complexities of mutual recognition limited to the chemicals sector. Rather, mutual recognition measures

_

²² Procter and Gamble, submission to European Commission

²³ Under the EU's "roadmap," the EU has signaled its intention, by 2020, to assess and include as a Substance of Very High Concern, all substances known to be carcinogenic, mutagenic, or toxic to reproduction, as well as those that are "persistent, bio-accumulative and toxic" (PBTs), endocrine (hormone) disrupting compounds (EDCs), and sensitizers.

threaten to impair effective regulation across a broad range of sensitive sectors, from chemicals to pharmaceuticals to cars. For example, the EU's initial position paper on Motor Vehicles in TTIP explicitly proposes that:

"[I]n order to facilitate trade and the recognition of the substantial technical requirements, EU type-approval authorities would be required to test US vehicles destined for the EU market against US regulations using US testing methods, while US bodies would, in their market surveillance activities, test EU vehicles against EU/UNECE regulations and their testing methods."²⁴

This would effectively require vehicle testing authorities in each party to maintain and operate two parallel systems for vehicle testing, depending upon the origin of the vehicle.

Mutual recognition provisions are only ever appropriate if they: (1) enhance the well-being of consumers; (2) are not applied in sensitive sectors involving public health, safety, or the environment; (3) are negotiated in open and accountable fora; and (4) are negotiated between countries having equally strong consumer safeguards, including mechanisms for public participation in domestic regulatory decision making and corporate liability structures.²⁵ These necessary elements are not met in the chemicals sector. Therefore, mutual recognition provisions should not be included for the chemicals sector and other sensitive sectors.

V. Investor-State Dispute Settlement

Investor-state dispute settlement would allow foreign corporations to bypass domestic courts and sue governments in private tribunals over laws and policies that the corporations allege reduce

²⁴ NOTE FOR THE ATTENTION OF THE TRADE POLICY COMMITTEE ON THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP, ANNEX 1--INITIAL POSITION PAPER: MOTOR VEHICLES IN TTIP, EC TRADE POLICY COMMITTEE (June 21, 2013). ²⁵ TACD BRIEFING PAPER, *supra* note 17.

their expected future profits. The inclusion of such extreme provisions in prior trade and investment deals has enabled powerful interests, from tobacco companies to corporate polluters, to use investor-state dispute resolution to challenge and undermine consumer, public health and environmental protections. Investor-state tribunals have ordered taxpayers to compensate foreign corporations for the domestic, non-discriminatory enforcement of such protections.

Investment provisions in existing free trade agreements, including the North American Free Trade Agreement (NAFTA), have facilitated a proliferation of legal challenges to bans on toxic chemicals, mining regulations, energy regulations, and more. 26 These rules have been replicated in various U.S. free trade agreements (FTAs), including the Central American, Peru and Oman FTAs, and the recently passed deals with Korea, Panama and Colombia. The inclusion of very broad investor protections, such as a guarantee of "fair and equitable and treatment," could open the door to investment cases when governments put in place new or amend existing laws and policies designed to protect the public interest.

Over US \$365 million in compensation has already been paid out to foreign investors in a series of investor-state cases under NAFTA-style deals.²⁷ This includes attacks on health and safety measures, natural resource policies, environmental protection, and more. Of the over US \$13.1 billion in the 16 pending claims under NAFTA-style deals, all relate to public health, environmental, energy, land use and transportation policies – not traditional trade issues.²⁸

Cases in recent years have demonstrated that companies are both willing and able to locate or relocate their foreign operations for the express purpose of choosing the most investor-friendly

²⁶ Table of foreign investor-state cases and claims under NAFTA and other U.S. trade deals: March 2013, PUBLIC CITIZEN, http://www.citizen.org/documents/investor-state-chart1.pdf (last visited Apr.11, 2013).

²⁷ Investor-State Attacks on the Public Interest, PUBLIC CITIZEN, http://www.citizen.org/Page.aspx?pid=5329 (last visited July 23, 2013). ²⁸ *Id*.

forum for potential trade disputes, regardless of whether they have a legitimate business nexus with the countries involved. More troublingly, tribunals in investor state disputes have proven willing to accept such "treaty shopping" as legitimate, provided it takes place before the formal initiation of a dispute. For example, in a case brought under the U.S.-Central American Free Trade Agreement (CAFTA), a Canadian mining corporation, operating in El Salvador through a subsidiary registered in the Cayman islands, sought recourse to U.S. investor protections under CAFTA by the simple expedient of deregistering its Cayman Islands subsidiary and reregistering the enterprise in Reno, Nevada. While the company's CAFTA claim was ultimately rejected on the ground that the company had abused the process by relocating to a CAFTA country during an active dispute, the panel opined that the issue was primarily one of timing: had the company registered in a CAFTA country prior to the onset of the dispute, even for the express purpose of getting recourse to the investor protections, it might have been accorded those protections under the agreement.²⁹ Not surprisingly, law firms and consulting firms have developed a thriving industry in advising corporations how to restructure to take strategic advantage of such "treaty shopping" opportunities. 30

²⁹ Pacific Rim Cayman, LLC. v. Republic of El Salvador, ICSID Case No. ARB/09/12, Decision on the Respondent's Jurisdictional Objections, June 1, 2012. § § 2.41.-2.52 See also Mobil Corporation and others v. Bolivarian Republic of Venezuela, ICSID Case No. ARB/07/27, Decision on Jurisdiction, 10 June 2010, § 204 ("As stated by the Claimants, the aim of the restructuring of their investments in Venezuela through a Dutch holding was to protect those investments against breaches of their rights by the Venezuelan authorities by gaining access to ICSID arbitration through the BIT. The Tribunal considers that this was a perfectly legitimate goal as far as it concerned future disputes.").

See, e.g., Calvin Chan, Structuring Oil and Gas Investments to Take Advantage of Substantive Rights under Investment Treaties, Skadden, Arps, Slate, Meagher & Flom (October 27, 2011), available at http://www.oilandgas-asiapacific.com/_assets/_slides/Calvin%20Chan%20Oil%20and%20Gas%20Investments.pdf; Baker & McKenzie, Opportunities in Structuring and Re-structuring Investments and Business Relationships. Presentation at Latin America 2010: Proactive Strategies for Doing Business in Today's Changing Landscape. (Miami, March 17, 2010), available at http://www.bakermckenzie.com/files/Uploads/Documents/ Locations/Latin%20America/pn_latax2010_01_opportunitiesstructuringinvestmentsbusinessrelationships_mar10.pdf.

The risk of such treaty shopping is compounded by the growing number of companies and individuals claiming, and receiving, investor protections on grounds that bear little resemblance to direct investment in a country. In a case still pending under NAFTA, for example, Mexican truck drivers have argued that they are entitled to investor protections under NAFTA's Chapter 11 because certification fees they pay to the Federal Highway Traffic Safety Administration qualify them as investors.³¹

To date, the United States has entered into more than fifty agreements according some form of investor protection. The EU member countries have concluded more than 1,200 such agreements. Notwithstanding the demonstrated risks of specious litigation, treaty shopping and attenuated and costly claims of investor protection under these existing agreements, both parties have declared an objective to go beyond any previous agreement to afford even greater levels of investor protection under TTIP. The extensive and troubling record of abuse under the existing system should raise grave concerns regarding that objective.

After Philip Morris' challenge to measures designed to protect citizens' health, Australia decided to discontinue investor-state dispute settlement mechanisms. The government's official position states: "Nor will the Government support provisions that would constrain the ability of Australian governments to make laws on social, environmental and economic matters in circumstances where those laws do not discriminate between domestic and foreign businesses." 32

2.

CANACAR v United States of America - Notice of Arbitration - NAFTA - 02 April 2009.

³² AUSTRALIAN GOVERNMENT, DEPT. OF FOREIGN AFFAIRS AND TRADE, GOVERNMENT TRADE POLICY STATEMENT (April 2011), *available at* http://www.dfat.gov.au/publications/trade/trading-our-way-to-more-jobs-and-prosperity.html#investor-state.

A potential agreement between the United States and EU must not include investor-state dispute resolution. If concluded, TTIP could be enforced through ordinary courts of the U.S. and EU. Because U.S. and EU property rights laws and courts are robust, there is no pretext for granting foreign investors superior rights to domestic firms or subjecting our judicial systems to tribunals empowered to put the American public in a lose-lose situation. The inclusion of such provisions would have a chilling effect on the future development of regulations for public health, safety and the environment in the EU and U.S.

To avoid such overreaching procedural and substantive investor privileges, greater than those afforded to domestic firms in either the United States or the EU, any deal must exclude investor-state dispute resolution.³³

VI. Preemption

Closely related to the question of harmonization and mutual recognition is the divergence of approaches to health, safety and environmental protection at various levels of governance at the sub-national or sub-regional level in the U.S. and EU respectively.

In the United States, over 30 states have enacted different measures to protect people and the environment from toxic industrial chemicals, due to the inability of the U.S. federal system to fill this role. California, Maine and Washington State are a few of States that have emerged as leaders in enacting measures to reduce exposure to toxic chemicals in products, food, water and the environment. Several submissions received in response to the various public consultations on the TTIP report on EU exporters' difficulties with accessing and understanding the rules they

³³ Letter to President Barack Obama, President José Manuel Barroso, and President Herman Van Rompuy from consumer and public interest orgnizations in the U.S. and EU, dated July 8, 2013, available at: http://www.citizen.org/documents/public-citizen-letter-to-obama-alerting-to-tafta-concerns.pdf

have to comply with to gain access to the US market, in particular where multiple layers of regulation.³⁴

According to initial position papers, the "EU considers that the aim of maintaining an overall balance of commitments in the TBT area can only be achieved if both the sub-regional (in the EU) and the sub-federal (in the US) regulations are covered."35 This expectation is set forth clearly and repeatedly as a central EU objective for the negotiated outcomes under TTIP. EU documents set forth a further position that the EU should be notified and consulted on any significant regulations at the sub-federal level that may affect trade, and that any such regulations should be held to a standard that avoids unnecessary interference with transatlantic trade. A range of state-level initiatives on toxic chemicals and other environmental issues could be preempted by various provisions of TTIP, which could also have a chilling effect on their future development. Indeed, a significant factor in this chilling effect could arise simply from the extensive and costly additional burdens such consulting obligations would impose on policymakers and regulatory authorities at the state and local level. In addition, provisions such as investor state dispute resolution could preempt sub-federal or sub-regional laws that are more protective of health, safety and the environment.

Regarding divergent approaches in the EU, the US Trade Representative and industry has complained about Member States interpreting provisions of REACH in ways that would lead to improved consumer protection. Efforts are also ongoing in EU Member States to take precautionary approaches to health, safety and environmental protection, for example in the creation of registers for manufactured nanomaterials and moratoria on the use of hydraulic

fracturing for shale gas extraction or 'fracking.' For example, a French initiative is in force for a mandatory register for nanomaterials that covers the entire supply chain is being imitated and expanded by the Danish, Belgian and Italian governments. In terms of moratoria on fracking, France, Germany, Spain, Bulgaria, Romania, and the Czech Republic, have placed moratoria on the use of this technology as a precautionary measure. These and similar efforts taking place at the state level here in the U.S. or at national level in the EU are at risk of being preempted by possible provisions of TTIP.

Of considerable concern in ongoing efforts to fix TSCA here in the U.S. is the inclusion of state preemption provisions in the Chemical Safety Improvement Act (S. 1009), the latest Senate proposal for reform, recently introduced by Senator Vitter and the late Senator Lautenberg. Likewise, provisions for investor state dispute settlement and other trade promotion measures, such as harmonization and mutual recognition, can also result in the preemption of laws for public health, environmental protection and safety at the state level in the U.S. and national level in the EU.

VII. Influencing the development of laws outside the U.S. and EU

Beyond its potential chilling effect on future regulatory advances in the United States and the EU, , a US.-EU trade agreement could have chilling effects on the development of regulations far outside these two economic superpowers, shaping and potentially slowing progress on environmental, health and safety standards in Eastern Europe, Asia and beyond.

The chemical industry has not hidden its displeasure with REACH from government officials in the U.S. or EU, and continues to complain about its costs, burdens and complexity. During the Bush Administration, a U.S. Commerce Department paper recorded that "[i]ndustry . . . would like the [U.S. Government] to work to educate [other countries] so that they can join the United States in raising concerns." In March 2002, Secretary of State Colin Powell sent a cable directing U.S. diplomatic posts to "raise the EU chemicals policy with relevant government officials" and to object to the REACH proposal as "a costly, burdensome, and complex regulatory system."

In addition to contesting REACH in the EU, the U.S. government and industry has been working to prevent the expansion of REACH-like policies outside the EU, especially where countries propose to go beyond what REACH currently requires. Despite these efforts, elements of the EU's REACH legislation continue to be adopted by countries outside the EU. These countries include countries with significant levels of chemical manufacturing and chemical use, such as China, Japan, Australia, Korea, Turkey, Taiwan, Vietnam, and Malaysia. In addition, India and Indonesia are each drafting national legislation that includes elements of REACH. It is worth noting that over the next two decades, worldwide chemical production is projected to double from 2010 to 2030, with 71 percent of this new production expected outside the OECD, especially among the so-called BRIICS countries.³⁸ Many of these countries are among those drafting and adopting chemical legislation similar to REACH.

But, in the case of Korea's version of REACH, K-REACH, while intensive lobbying efforts did not prevent the adoption of a REACH-like system, they did result changes to the legislation that

³⁶ The Chemical Industry, The Bush Administration, and European Efforts to Regulate Chemicals, House Committee on Government Reform, report prepared for Rep. Henry Waxman (2004), available at: http://oversight-archive.waxman.house.gov/story.asp?ID=427

 $^{^{38}}$ Organisation for Economic Cooperation and Development, OECD Environmental Outlook to 2050: The Consequences of Inaction (2012).

would otherwise have afforded greater protection than REACH itself. Provisions of the U.S.-Korea FTA were used to seek revisions to the proposed Korean law, such as an increase in the *de minimis* production volume exclusion from 0.5 tonnes to 1.0 tonnes, a potential impediment to accessing information about speciality chemicals, such as manufactured nanomaterials, that may be manufactured in commercially significant volumes while still falling below these tonnage requirements.

Regardless of the adoption and ongoing implementation of REACH in the EU, the chemical industry is viewing TTIP as an opportunity to establish a global standard for chemicals regulation at the national or regional level by decreasing regulatory divergence between two of the three major chemical countries or regions of the chemical industry. Procter and Gamble states that "[a]n ambitious agreement between the EU and US would create a major opportunity to set an example for the articulation of other countries' regulatory systems, in particular of BRICs countries."³⁹ To the extent that TTIP results in stronger levels of protection in the U.S. for human health, safety and the environment, and does not delay the implementation of REACH, this could be a positive development. Anything less, however, would have a chilling effect on the development of chemical regulations outside the EU that impose measures more stringent than the EU or U.S.

VIII. Conclusion

To conclude, we would first like to offer some comments on the process moving forward. Since NAFTA, the United States has conducted its trade negotiations with other countries and regions in a in a manner that does not satisfy the requirements of transparency in a constitutional

³⁹ Proctor & Gamble submission to COM.

democracy, despite the profound implications of these negotiations for public health, well-being and the environment. To date, negotiations between the United States and the EU have followed a similar path. Although the EU's public disclosure of its initial negotiation positions has been a small but positive step in the right direction, the EU's recent release of a letter describing its confidentiality practices for the negotiations raises serious questions as to whether even the current, limited levels of transparency will continue as the negotiations progress.

The secrecy and opacity observed in other trade negotiations, including the negotiations for the Trans Pacific Partnership, are inconsistent with basic principles of good governance and with the public's right to informed, meaningful participation in what amounts to a public policy dialogue of profound national consequence on both sides of the Atlantic. Negotiations between the United States and the EU should demonstrate a clear commitment to public participation and should be conducted in an open, transparent and participatory manner. Specifically, the United States and the EU should commit to broad public access to negotiating documents and positions, to facilitate informed public debate regarding the negotiations and any resulting agreement.

In their communications with the public, both the United States and the E.U. have communicated an interest in defining a "positive" trade agenda--one in whichincreased trade mutually supports environmental protection and social development, and does not come at the expense of environment or labor rights. The EU outlines a number of goals that might be achieved in such an agenda, and explicitly acknowledges as a fundamental element of sustainability the need to recognize "each party's right to define and regulate its own domestic levels of environmental and labor protection at the level deemed necessary." Language on effective domestic

.

⁴⁰ Trade and Sustainable Development: initial EU position paper, EC (2013), available at http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc 151626.pdf.

implementation of internationally agreed environmental principles, suggests a view that convergence must result in a regulatory floor that bolsters consumer interests, not a regulatory ceiling that constrains them. Disincentives for trade in illegal products, and incentives for those that are truly sustainable, also show promise for building a positive trade agenda.

However, other provisions point to a high-level of emphasis on evaluating the potential impacts of environmental and labor provisions on trade. End of the day cost-saving to consumers from trade agreements that lower consumer and worker safeguards are modest at best, while the cost of inaction on health, safety, labor and environmental concerns borne by the public-at-large are staggering at present, and grow with each passing day. Even using consistently over-estimated costs of regulation and benefits of deregulation or harmonization, these estimates do not come anywhere close to the cost of inaction on public health, safety, labor and environmental issues that are at risk from a trade agreement that puts trade ahead of the public interest.

Thank you, again, for the opportunity to testify on this critical issue. CIEL and our partners look forward to working with US lawmakers and officials in an open, transparent and participatory manner, as they explore whether an agreement is possible that increases trade while being mutually supportive environmental protection and social development, and does not come at the expense of environment or labor rights.

⁴¹ See e.g. Public Citizen, *TAFTA's Trade Benefit: a Candy Bar* in Eyes on Trade (blog) (July 11, 2013), available at http://citizen.typepad.com/eyesontrade/2013/07/taftas-trade-benefit-a-candy-bar.html (quoting a study that finds that "the trade-related benefits we should expect from TAFTA amount to...an extra three cents per person per day...starting in 2029"). Compare to, UN Environment Program, Cost of Inaction (2012) (costs of certain hazardous chemicals with data estimated at hundreds of millions to tens of billions of dollars annually to people and governments); and Nicholas Stern, Stern Review on the Economics of Climate Change (2006) (calculating that the level of inaction in 2006 on climate change will be equivalent to losing at least 5% of global gross domestic product (GDP) each year, now and forever. When including a wider range of risks and impacts, GDP losses could increase to 20% or more, also indefinitely).

⁴² See e.g. The International Chemical Secretariat, Cry Wolf: Predicted Costs by Industry in the Face of New Regulations (2004), available at http://www.chemsec.org/images/stories/news-publications/ Cry wolf report 040422.pdf