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Toxic partnership

A critique of the ACC-CEFIC proposal for trans-Atlantic cooperation on chemicals

Executive Summary

An unprecedented trade agreement is being negotiated between the European Union (EU) and the United States (US).

The proclaimed aim of the proposed Trans-Atlantic Trade and Investment Partnership (TTIP) is to increase trade between the two trading blocs through the minimization of technical barriers to trade (TBTs). According to economic estimates used by the European Commission, the chemicals sector would be the second biggest beneficiary of "full liberalization" through TTIP.[1] For over a decade, the US government and the chemical industry have claimed that EU chemicals legislation is a major barrier to trade, due, in part, to the deep divergence in levels of protection afforded by the regulatory regimes in the two trading blocs.[2]

In advance of the December 2013 round of EU-US trade negotiations, the trans-Atlantic chemical industry secretly proposed draft text on regulatory co-operation for negotiators to consider including in TTIP.

The joint proposal by the American Chemistry Council (ACC) and the European Chemical Industry Council (CEFIC) seeks to use TTIP as a mechanism to "address the potential non-tariff barriers that can arise from discordant regulatory measures". While this may appear to be a reasonable aim on its surface, closer study of the proposal strongly suggests different motivations – to exploit regulatory differences between the two parties to slow regulatory developments at all levels, prevent the regulation of endocrine disrupting chemicals (EDCs) and obstruct efforts to promote substitution of all harmful substances with safer alternatives. Industry's suggestion that its proposed "improvements" purport to involve no changes in the underlying statutory or regulatory requirements in either jurisdiction are, at best, wildly implausible and, at worst, deeply disingenuous.

According to the UN Environment Programme (UNEP), trans-Atlantic production and use of chemicals stand to increase by over 20% by 2020— even without TTIP.[3] Unfortunately, according to Eurostat, 62% of the total production of chemicals are toxic chemicals.[4]

This paper provides a critical analysis of, and response to, the trans-Atlantic chemical industry's proposals for regulatory cooperation under TTIP. It demonstrates that, rather than improving the regulation of chemicals, their suggestions are likely to:

- Freeze progress in regulating toxic chemicals;
- Create an industry bypass around democracy;
- Give commercial interests and trade precedence over the protection of human health and the environment;
- Stifle innovation in safer chemicals; and
- Impede global action on toxic chemicals.

The proposals by ACC and CEFIC aim at nothing less than manipulating the pace and direction of chemicals regulation in the EU and US through the inclusion of specific language and content in TTIP; language crafted to benefit the chemical industry, not public health or the environment. These proposals would delay the development of stronger rules for hazardous chemicals in the US and EU, and undermine democratic principles that underlie two of the world's largest economies.

There is not a single idea in this proposal that could increase efficiency of trade between the two blocs, nor reduce costs to governments. Instead, it would create additional committees at further cost to the taxpayers and interject new barriers to necessary regulation at all levels of government that would reduce regulatory efficiency and efficacy. Further, the financial burden to society would continue from industry's continued externalization of the costs of toxic chemicals, including damage to human health and remediation.

We call on the European Commission and negotiators of the agreement to clearly reject all proposals from the chemical industry that are not compatible with the EU commitment to implement by 2018 a strategy for a non-toxic environment that is conducive to public health, innovation and the development of sustainable substitutes. On this basis, including a US commitment to systematically phase-out hazardous chemicals and a bilateral commitment to discussions that are truly transparent and open to public input, trans-Atlantic cooperation could begin to achieve regulatory convergence. Absent such commitments, ongoing negotiations on chemicals within TTIP must be rejected as a serious threat to public health and environmental safety and an abnegation of a fundamental government responsibility on both sides of the Atlantic.

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Summary of key concerns

The proclaimed aim of the proposed Trans-Atlantic Trade and Investment Partnership (TTIP) is to increase trade between the European Union (EU) and the United States of America (US), primarily through the minimization of non-tariff or technical barriers to trade (TBTs). Trade negotiators claim that both jurisdictions will retain the "right" to regulate in the public interest. The ACC-CEFIC proposal states that no changes are contemplated in the underlying statutory or regulatory requirements in either jurisdiction. However, this assurance is wildly implausible and, at worst deeply disingenuous. Closer cooperation between the two regimes will inevitably influence and guide the way in which regulatory bodies fulfil their mandates to protect health and the environment. These risks are particularly severe in areas, such as chemicals policy, where both the regulatory approaches and regulatory outcomes are widely divergent. Indeed, the proposals advanced by industry appear more finely tailored to exploit those differences than to remedy them in the name of more effective, more protective regulation. This danger is seen throughout each of the chemical industry's proposals considered in the sections below.

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Freeze progress in regulating toxic chemicals:

The ACC-CEFIC proposal promotes the co-ordination and harmonization of regulatory approaches through a trans-Atlantic "Cooperation Committee" of EU and US regulators for the chemical sector.

Through the creation of a Regulatory Cooperation Council with authority to address, slow, and skew all critical decisions in regulatory processes that can result in restricting the use of toxic chemicals, regulatory cooperation under TTIP would slow and, in many cases, freeze chemicals regulation. These critical decisions include: how much scientific evidence is necessary and sufficient to regulate toxic chemicals; methodologies and approaches to hazard and risk assessment; the types and number of chemicals for regulators to prioritize in regulatory review processes; the level of precaution used for endocrine disruptors and other "emerging" hazards; data quality requirements regarding the use of cutting-edge research; the amount of data required to gain approval for chemicals to be marketed; and more. Many of these activities have already been completed, or unsuccessfully attempted, within the OECD's existing (and multilateral) regulatory cooperation efforts on chemicals.

This paper highlights the long-standing and deeply divergent positions, and progress, of the EU and US in the regulation of toxic chemicals. As a result, any attempt to align current approaches to regulation and science-based decision-making will chill and, ultimately, freeze the process of developing necessary chemicals regulation.

Create an industry bypass around democracy:

In both the US and the EU, established democratic procedures allow a degree of public engagement and allow citizens the opportunity to influence the direction of regulatory policy. The industry proposal endorses and builds upon the EU's proposal to create a Regulatory Cooperation Council, a trans-Atlantic body where half of the members would have no mandate from, or responsibility to, the public most affected by their decisions and in which the perspectives of other stakeholders would be wholly absent. Proposals by industry patently do not include civil society as a stakeholder in the process of regulating the manufacture and use of toxic substances. Disregard for the public interest has also been demonstrated by the chemical industry's access to the negotiations that have otherwise been characterized by a lack of public transparency and the fact that industry's lobbying proposals and government position papers have only come to light through leaked documents.

Give commercial interests and trade precedence over the protection of human health and the environment

In pursuing new markets, a number of industry's proposals are likely to circumvent the primary purpose of chemicals regulation: to protect human health and the environment.

Proposals to introduce mandatory assessments of the costs and benefits of proposed regulations, including the impact on trans-Atlantic trade, risk adding an unhelpful, time-consuming, imbalanced, and costly stage to the regulatory process at the expense of protecting public interest. These impacts are likely to be felt most acutely at the Member State level in the EU and state level in the US. Cost-benefit analyses typically fail to consider natural resource damage, loss of productivity due to diseases and disorders of environmental origin, and other costs of toxic chemicals. The numbers are skewed such that cost-effectiveness is defined by the economic impact on the regulated industry, not the externalized costs borne by individuals and government resources.

The ideas proposed by industry in relation to information sharing, mutual recognition of minimum data requirements between the EU and US to gain access to markets, and confidential business information would directly contradict the fundamental principle of REACH: "No data, no market". They would also restrict the public's "right to know" chemical safety information, including restricting access to information by regulators themselves on the grounds of protecting confidential business information. EU and US approaches to the "right to know" differ significantly, but the proposal would undermine the public's right to know under REACH and be in conflict with provisions with a similar objective in the Aarhus Convention.

Stifle innovation in safer chemicals

There is no mention in the ACC-CEFIC proposal of any intention to reduce the manufacture or use of harmful substances, despite estimates of staggering health care and other costs externalized by industry on individuals, governments, and businesses.[5] Stronger chemical laws drive innovation and enable safer chemicals to enter the market.[6] The European Commission's own assessment of the impact of REACH showed that hazard-based elements of the REACH regulation are the current driver for change at the present. Recent announcements by major downstream users of chemicals and retailers (e.g. Johnson & Johnson and Walmart) to eliminate certain hazardous chemicals before government action, building goodwill among consumers and gaining first-mover advantages over their competitors, clearly illustrate this trend. Given the ability of developing countries to compete effectively with the EU and US in the manufacture of bulk chemicals, the future of the trans-Atlantic chemical industry is not in mass production of hazardous substances, but rather leading the transition to safer chemicals. Proposals by the chemical industry would stifle the potential of stricter rules in the US and EU to drive innovation toward safer chemicals, and continue to externalize the costs of toxic chemicals to society at large.

Impede global action on toxic chemicals

In today's chemical-intensive economy, strong global standards are essential to protect people and the environment in the EU and US from toxic chemicals. Submissions by the chemical industry claim that TTIP would help to create global standards. However, the proposals put forward by the US and EU chemical industry would likely result in weaker standards globally in the long term. US and EU governments cannot unilaterally protect their populations from toxic chemicals entering from outside their borders, whether they arrive embedded in traded products, including food, or deposited through long-range environmental means like wind and water.[7]

Recent reports by OECD and UNEP project that the trend of rapidly accelerating chemical production and use outside the U.S. and Western Europe will continue through the remainder of this decade, and likely beyond.[8] According to the chemical industry, the driver for this growth is not the weakness or stringency of chemical laws, but rather proximity to feedstocks and downstream users of chemicals (e.g. manufacturing facilities).[9]

International progress over the past several decades on reducing the use of toxic chemicals has derived from progress in either the US or Europe; seldom, if ever, has this progress been in unison. Beyond its potential to freeze regulatory advances in the United States and the EU, a TTIP could also stifle the development of much-needed controls of chemicals around the world.

... And More

It is important to note that regulatory cooperation is not the only aspect of TTIP that threatens to have a chilling effect on regulation, to undermine democracy and to stifle innovation. TTIP also aims to "improve" conditions for investment. The possible inclusion of provisions for Investor-State Dispute Settlement (ISDS) to reinforce this goal also threatens these vital elements of a

better future, free of toxic chemical contamination and other environmental and social injustices. This paper does not address the concerns of ISDS in this regard, but rather focuses on the proposals secretly submitted by chemical industry trade associations for regulatory cooperation to address TBTs.[10]

Analysis of the trans-Atlantic chemical industry's joint proposal

In advance of the December 2013 round of EU-US trade negotiations, the trans-Atlantic chemical industry, through the American Chemistry Council (ACC) and European Chemical Industry Council (CEFIC), secretly proposed draft text for negotiators to consider including in TTIP on "regulatory cooperation" in addressing the use of toxic chemicals in the EU and US.[11]

Public interest advocates have long criticized the bias and secrecy with which trade agreements are negotiated. The chemical industry's proposal was not disclosed publicly and came to our attention as leaked documents. However, the proposal was discussed by EU and US negotiators during the third round of negotiations. This briefing analyzes in detail the proposal from the chemical industry.

For over a decade, the US government and the chemical industry has claimed that EU chemicals legislation is a major barrier to US exports, due, in part, to the steep divergence in levels of protection between the two trading blocs (see Table 1).[12]

Table 1: Elements of EU laws and policies for toxic chemicals vs. the US policy for toxic chemicals (various sources)

Element	EU	US
Chemical manufacturers must prove the safety of industrial chemicals on the market?	Yes	No
Laws clearly identify classes of chemicals that are not socially acceptable, and enable their systematic substitution?	Yes	No
Generally prohibit pesticides and biocides that are CMRs, PBTs, vPvB, EDCs, or of equivalent concern?	Yes	No
Government authorization required for specific uses of industrial chemicals that are CMRs, PBTs, vPvB, EDCs or of equivalent concern?*	Yes	Yes
Complete internalization by industry of the costs of chemical pollution	No	No
Requires reporting on uses of industrial chemicals up and down the value chain?	Yes	No
Minimum level of health and safety data required for industrial chemicals?	Yes**	No

*CMRs are chemicals that are carcinogens, mutagens or toxic to reproduction; PBTs are persistent, bioaccumulative and toxic chemicals; vPvB are those that are very persistent and very bioaccumulative; and EDCs are endocrine (hormone) disrupting chemicals.
** Data requirements are tiered based on tonnage.

The ACC-CEFIC proposal seeks to use TTIP as a mechanism to "address the potential non-tariff barriers that can arise from discordant regulatory measures".[13] While this may appear to be a reasonable aim, closer study of the proposal reveals different motivations to exploit existing differences between the EU and US systems to raise new hurdles to legitimate regulatory processes, prevent the regulation of endocrine disrupting chemicals (EDCs) and obstruct efforts to promote substitution of all harmful substances with safer alternatives. The proposed "improvements" purport to involve no changes in the underlying statutory or regulatory requirements in either jurisdiction.

The industry proposal included specific wording for the chemical sector "annex," together with draft wording for "horizontal issues" on TBTs, including the following elements:

1. Regulatory cooperation, including the establishment of a Chemical Sector Joint Cooperation Committee (CSJCC);
2. Enhanced scientific cooperation when developing regulations through a scientific body and the increased use of cost-benefit analyses (i.e. impact assessments);
3. Harmonized risk and hazard assessment methodologies, including data requirements;
4. Common prioritization;
5. Greater coherence in classification and labelling;
6. Mutual acceptance of registrations and notifications for new chemicals;
7. Aligning regulations on "emerging issues" such as endocrine disrupting chemicals (EDCs) and nanomaterials; and
8. Data sharing and the protection of confidential business information (CBI).

These elements of ACC and CEFIC's proposal are analyzed below.[14]

1 Regulatory co-operation

The chemical industry's proposal for regulatory cooperation under TTIP must be read in the context of the EU's own proposal for regulatory cooperation, which raised similar concerns over inadequate transparency when it was disclosed through an unauthorized leak (Annex 2). Accordingly, this report first assesses the EU's own proposal to create a "Transatlantic Regulatory Cooperation Council" before turning to an analysis of the chemical industry's more specific suggestions.

1.1 Regulatory Cooperation Council

One of the major features of TTIP is the creation of a framework and institutional basis for future regulatory cooperation. The European Commission position paper on regulatory cooperation suggests the creation of a Trans-Atlantic Regulatory Cooperation Council (RCC) to oversee the development of regulatory processes on both sides of the Atlantic, with the goal of avoiding or minimizing regulatory differences.[15]

The RCC will cover all measures of general application which have the potential to impact trade. Its scope of work would include all levels of decision-making, including, for the EU, delegated acts.[16] The scope would also extend to regulations by EU Member States or by individual US

states. Although it is stated that the right to regulate would be recognised, this would limit the ability of Member States in the EU and of US states to develop more protective laws on chemicals within their jurisdiction. Due to the badly broken US TSCA, over 30 states have taken action on industrial chemicals. States like California, the twelfth largest economy in the world, are actively implementing policies to encourage innovation through the substitution of toxic chemicals with safer alternatives. In the United States, individual states have always been laboratories for developing and testing new policy approaches, and chemicals policy is no exception. For example, state action to phase-out toxic flame retardants led to a federal phase-out. These and other types of state-level initiatives in the U.S. would be put at risk by the EU's proposal for regulatory cooperation.

The proposed creation of an overarching, trans-Atlantic body of regulators by the EU (the RCC), with or without a subsidiary body for the chemical sector, poses the significant risk of slowing lawmaking processes, increasing demands on cash-strapped environmental health and safety agencies at both the federal and state levels, and undermining democracy in a critical area of public policy. There are two main concerns, which are not only limited to chemicals policy.

First, the regulatory cooperation council proposed by the EU would slow the development and implementation of legislation. Based on the EU position paper, regulators in the US would have to undergo onerous consultations with trans-Atlantic counterparts, including time-consuming and unreliable cost-benefit analyses.[17] Significantly, these requirements would apply not only to national regulators, but to regulators at the state level, where international consultation requirements could pose an even heavier burden on comparatively smaller regulatory resources. The EU did not describe the processes that EU legislators and regulators--including regulators in EU Member States--would need to follow to consult with US counterparts, but it is fair to assume it would be at least as onerous.

Second, it raises profound questions of democracy. A fundamental tenet of democratic governance is that all citizens should have an equal voice in matters of public policy that affect them. For citizens on both sides of the Atlantic, the RCC undermines that tenet. It would remove important public policy choices from the public sphere--and from public processes--in each party, and subject them to scrutiny by regulators whose mandate, responsibility and loyalty lies with the citizens of another country, an ocean away. That laws developed through democratic processes of one party would be subject to the scrutiny of regulators that have not been elected or appointed by that party, raising serious concerns regarding democratic decision-making with respect to which chemicals each party's citizens are willing to accept in their environment and in their bodies.

1.2 Chemical Sector Joint Cooperation Committee (CSJCC)

ACC-CEFIC proposes the establishment of a Chemical Sector Joint Cooperation Committee (CSJCC), (as a subsidiary body of the RCC) to minimize regulatory differences in the chemical sector. Its mandate would include sensitive matters such as: the application of scientific standards for hazard and risk assessment, mutual recognition of widely divergent safety and data requirements to place chemicals on the market, common issues of prioritization, as well as

the issues of classification and labelling, all of which are core to the operation of a regulatory framework for chemicals.[18]

These decisions are essential to progress under chemicals legislation, in both the US and EU, which typically gives discretion to regulatory authorities, subject to checks and balances. With or without the creation of the CSJCC, when read in light of the EU position paper on regulatory cooperation, the ACC-CEFIC proposal would chill the development of chemicals legislation on both sides of the Atlantic, shield hazardous chemicals from tighter controls and undermine democracy in deciding what threats are acceptable to the society at risk.

2 Scientific Co-operation

To enhance scientific cooperation in the development of regulations, ACC-CEFIC propose: (1) the creation of a joint scientific advisory committee (and possible temporary or standing scientific working groups); and (2) "regulatory impact assessments" that estimate various costs and benefits of proposed regulations and alternative scenarios, with a special focus on international trade.

2.1 Trans-Atlantic Scientific Advisory Committee

ACC and CEFIC propose the establishment of a Trans-Atlantic Scientific Advisory Committee (TSAC) to support and, more importantly, to *validate* cooperative efforts between regulators. The TSAC would "promote common trans-Atlantic understanding of scientific evidence" and "utilize the experience of scientific committees on both sides of the Atlantic."[19] TSAC would "form the basis for Trans-Atlantic regulatory cooperation grounded in common scientific evidence and assessment."

The text proposes that, within the TSAC, there should be agreement upon an evaluation framework for decision making, which: (a) uses sound and objective and internationally validated scientific practices in assessing risks, and (b) considers best available science, including a description of the "weight of the scientific evidence". There should also be agreement upon criteria for selecting data and information sources when making regulatory decisions.[20]

Industry calls for "scientific" or "science-based" evidence and assessment are longstanding. They reflect the chemical industry's continued refusal to accept that the interpretation of complex data, as foreseen in a risk assessment of a chemical compound, where all evidence must be weighted, may lead to different conclusions depending on how different elements of the evidence are weighted. Further, it reflects the continued reluctance on the part of industry--and, regrettably, many U.S. political leaders--to embrace the precautionary principle, which recognizes that the lack of full scientific certainty must not be used as an excuse to avoid cost-effective measures to protect the environment and human health when there are threats of serious or irreversible damage.[21]

The recognition that there is always uncertainty, even in the face of the overwhelming evidence, is an inherent and fundamental characteristic of the scientific method. Not surprisingly, then, the existence of absolute consensus within the scientific community on any issue is the rare exception, rather than the norm. Thus, to translate environmental and public health research into policies that aim to prevent harm, credible evidence of harm, rather than incontrovertible proof, should be adequate to overcome these inevitable scientific uncertainties. The degree of evidence warranted is, however, not for industry or scientists to decide, but rather the public through democratic systems. All precautionary decisions are reversible, but the social and economic costs for citizens, workers and the environment are often irreversible.

The challenge of uncertainty, and the need for precaution, is particularly evident in the chemicals context, where the complexity of biochemical interactions, exposure pathways, and wide variations in susceptibility among different populations and even different individuals within those populations, make it even more difficult to reach complete scientific consensus with respect to particular toxic risks. These disagreements often transcend national or regional boundaries.

It is worth noting that, despite fierce opposition and pressure by industry advocates, there are few, if any, reliable examples in which precautionary measures have been taken with respect to chemicals which were subsequently proven to be safe. This is due to a very timid application of this principle and thus decisions are always only taken after sufficient evidence is gathered.[22]

Nonetheless, the inevitable scientific uncertainties can be—and have routinely been—manipulated to delay needed regulatory action even in the face of substantial evidence of public harm (i.e. insufficient precaution).

In the US, one of the most startling examples of using scientific bodies to delay regulatory action is EPA's Integrated Risk Information System (IRIS).[23] IRIS assessments are frequently used by regulators - at the EPA, in the 50 US states, and around the world - to set health-based standards for chemicals.[24] The Center for Progressive Reform found roughly 500 chemicals in the public IRIS database, with as many as 400 waiting for at least ten years for initial or updated chemical risk assessments.[25] For some known chemicals of concern, the wait was much longer. Trichloroethylene (TCE) is generally acknowledged to be "highly" likely to cause cancer by numerous authorities around the world.[26] The IRIS assessment of TCE took 22 years.[27] These very problems with risk assessments led to the EU's adoption of REACH in 2006.

Industry's manipulation of scientific bodies can serve to delay the translation of scientific evidence of the risk of harm into meaningful policies. The ACC and CEFIC proposal to create a Trans-Atlantic Scientific Advisory Committee has no other added value than further delaying the development and implementation of more protective laws generally, without the likelihood of helping to resolve scientific disagreements.

2.2 Impact assessment (cost-benefit analyses)

In line with the EU position paper on regulatory coherence, ACC-CEFIC proposes mandatory impact assessments of various costs and benefits of proposed regulations and less burdensome

alternatives, including the potential impact on trans-Atlantic and international trade.[28]

The need for cost-benefit analyses in the US has prevented US EPA from using its legal authority to restrict or ban the use of toxic industrial chemicals. EPA promulgated a rule in 1989 prohibiting the future manufacture, importation, processing and distribution of asbestos in almost all products.[29] Despite overwhelming evidence of its harm to public health, an appeals court held that EPA did not present sufficient evidence of costs and benefits to justify its ban of asbestos.[30] In the quarter century since the court's decision, EPA has exercised its authority to ban or limit the production or use of an existing chemical only once[31]—in 1990.[32]

Any law which sought to limit the use of a chemical as an imported substance, or part of an article, would, inevitably, have an impact on international trade, except for the very limited circumstances where the exporting party already had an export restriction in place. There is already a high burden (insurmountable in the US) of proving the benefits of restricting the marketing and use of chemicals. The ACC-CEFIC proposal for TTIP to include "impact analyses" through the lens of effects on international trade could provide a legal basis for yet another obstacle to the development of protective measures for citizens and the environment.

3 Hazard and risk assessment methodologies

ACC-CEFIC proposes that the CSJCC should be used to develop hazard and risk assessment methodologies (including data quality requirements), together with a joint register of mutually accepted preferred testing methods, based on OECD Testing Guidelines. This would result in guidelines for (a) developing and implementing a structured framework for chemical evaluation using science-based criteria; (b) assessing risks based on sound and objective scientific practices; (c) promoting the use of the most current and best publically available science (including peer-reviewed studies); (d) considering the potential for threshold doses below which no adverse effects occur; and (e) considering the weight of the scientific evidence concerning such hazards, exposures or risks, including evidence of modes of action and adverse outcome pathways.

3.1 Test methods

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 US and EU, such as in Asia and Latin America, harmonization discussions should take place in broader multilateral fora, not in the narrow confines of bi-lateral discussions.

The proposals in relation to TTIP would add nothing to this well-established process. Indeed, it could operate to undermine globally harmonised efforts to generate data on chemicals through mutually accepted methods. Moreover, industry on both sides of the Atlantic should act on the

basis of global recommendations for more protective test methods, such as those contained in the 2012 Report by the World Health Organization, "State of the Science of Endocrine Disrupting Chemicals."

3.2 Evaluation of chemicals

The ACC-CEFIC proposal calls for the development of a structured framework for the evaluation of chemical risks. From a practical point of view, the chemical industry's proposal--that the parties develop guidance for the evaluation of chemicals--requests something already envisioned under existing EU law and, indeed, something that is generally done in risk assessment. Further, the European Chemicals Agency has already cooperated with industry stakeholders (including US companies with interests in the EU) to develop various guidelines and methodological approaches. There is little public benefit in expending additional resources to duplicate these efforts, whatever the perceived benefit to the chemical industry of doing so.

One fundamental difference between US and EU approaches to chemical management lies in who bears the burden of proving the safety of chemicals, and at what point this is required, in the chemical's approval process. Since its adoption in 2006, REACH has required the company that places any substance on the market above certain volumes, as part of the initial registration phase under REACH, to provide evidence necessary and sufficient to prove that the substance is safe, prior to its introduction on the market. If a substance is of very high concern,[33] proof is required that it either can be used safely for a specific use or that the benefits of the continued use of the substance outweigh the cost for society. Under the TSCA, by contrast, the U.S. chemical management system places the burden of proof on the regulators (and thus, on the public), rather than on the commercial interests seeking to bring a chemical to market. Specifically, US regulators must prove industrial chemicals pose an unreasonable risk; ironically, however, regulators cannot compel manufacturers to generate the health and safety data needed to demonstrate that risk unless an unreasonable risk is shown—a classic catch-22.

Under EU law, there is a very strong presumption against the use of hazardous chemicals. Substances of Very High Concern (SVHC) are identified on the basis of their intrinsic hazards, without a need to actually prove exposure to the public or to the environment. SVHCs include chemicals that are carcinogenic, mutagenic or toxic for reproduction, as well as chemicals that are PBTs[34] and vPvBs[35]. They also include substances identified on a case by case basis because of the equivalent level of concern about their harmful properties, such as endocrine disrupting chemicals.

Where a chemical is shown to be hazardous, REACH promotes the substitution of SVHCs with safer alternatives, even those chemicals that could, in some theoretical sense, be used safely. Similarly, hazardous pesticides and biocides are also prohibited, acknowledging that their risks cannot be managed in an environmentally sound manner. In doing so, the EU has adopted a hazard-based approach to the identification and substitution of substances of very high concern.

The EU approach is a substantial, but necessary, step towards reducing the use of, and exposure to, hazardous chemicals, necessitated by both the failure of previous legislation based

solely on risk assessment and by the lack of reliable information on uses of, and exposure to, most chemicals. Risk assessments are weak, not only because of the lack of reliable exposure information, but also because risk assessment generally does not take into account cumulative or synergistic effects of chemicals, or more highly vulnerable subpopulations like the developing foetus, workers, or communities that have been exposed the most for the longest period of time. 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."[36]

There is no parallel mechanism under US laws for pesticides and industrial chemicals. The US continues to rely on risk-assessment to ineffectively limit the use of hazardous chemicals. Risk is determined as a function of a chemical's intrinsic hazards, its use, and expected levels of exposure. In the US, however, most existing chemicals still lack toxicity data relevant to hazard assessment.[37] Regarding exposure, data is also 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, 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.

In sum, while the specific risk assessment methodologies applied within the two systems bear important similarities, the regulatory triggers for gathering and generating environmental health and safety data differ profoundly between the two systems--beginning with the fundamental question of who bears the burden of proof with respect to a chemical's safety--and when. Put simply, the European system is stricter,[38] more precautionary, more realistic and, ultimately, more protective of human health and the environment.

3.3 Data quality

The chemical industry also calls for agreed criteria for the assessment of the quality of data.

Recently, the European Chemicals Agency (ECHA) completed a first round of compliance checks of about 5% of dossiers submitted under REACH through December 2010, representing high production volume chemicals and/or substances that are CMRs. The compliance checks revealed that the chemicals industry submitted very low quality data to demonstrate safe use of these chemicals in the EU. ECHA found 69% of dossiers not in compliance; a clear indicator that industry is systematically failing to ensure that data of the highest quality is provided for regulatory purposes.

Rather than calling for methodologies to improve the actual quality and extent of data, a close reading of the ACC-CEFIC proposal suggests that the chemicals industry is actually seeking three things: a shared list of mutually recognised test guidelines; for good laboratory practice (GLP) to be the preferred standard for testing laboratories; and for common criteria for weight of evidence assessment. A shared list of mutually agreed test guidelines has been and can be

developed through OECD processes.[39] GLP is designed with industry scientists in mind as an antifraud system. GLP procedures are often difficult if not impossible for leading researchers to follow when developing new and improved test methods. It must be noted that REACH already foresees that tests must be carried out according to GLP principles or equivalent, internationally recognised, standards.

As for weight of evidence, it is true that there are no internationally established guidelines or criteria on how to reach a decision based on a weight of evidence approach. But the way in which evidence is weighted depends also on how uncertainties are expressed and taken into account. The strength of evidence is inversely related to the degree of uncertainty. Therefore, due to the different approach between the EU and the US in dealing with uncertainties, common procedures with respect to weight of evidence may not be possible.

4 Prioritization

ACC-CEFIC proposes that the parties establish a mechanism to document and share prioritization procedures and cooperate on identified priorities. Each list of regulatory priorities should be published by and shared between regulatory authorities.

Again, industry is essentially proposing to discard or ignore a mechanism that already exists and to re-establish it along lines more favourable to perceived industry interests. REACH either includes criteria for prioritizing chemicals for assessment and for phase out or these criteria are discussed and approved in committees that are open to industry and public interest stakeholders and discussed with all relevant actors (Member States, European Commission). In particular the Member States Committee at ECHA has the responsibility to take a large number of decisions on the prioritization of chemicals for assessment and phase-out.

4.1 Chemicals for in-depth assessment

The EU's Community Rolling Action Plan (CoRAP) is a list of substances that undergo evaluation by Member States. The original plan was for the CoRAP to include 950 substances by 2021. Chemicals are included in the list on the basis of risk concerns. Evaluating Member States are entitled to request companies registering the substances to provide further information, outside the scope of the standard information requirements, in order to prove the safety of the substance. After this evaluation, risk management measures could be proposed. In the first two years of CoRAP implementation, a total of 72 substances were evaluated: 36 substances in 2012; 46 in 2013.

The corresponding priority list for industrial chemicals in the United States is reflected in the EPA's "action plans" and "workplan". Action plans summarize available hazard, exposure, and use information on chemicals; outline the risks that each chemical may present; and identify the specific steps the Agency is taking to address those concerns. Ten classes of chemicals have EPA action plans, influenced heavily by actions taken on these chemicals by the EU and by the

179 parties to the Stockholm Convention on Persistent Organic Pollutants (POPs). The US is one of the few countries that has not ratified or acceded to the Stockholm Convention.

EPA's workplan lists 83 chemicals or classes of chemicals. Since 2012, EPA has produced draft risk assessment for only 5 of the suspected bad-actors in its workplan.[40] The glacial pace of evaluation by the US is of serious concern for trans-Atlantic cooperation around regulatory prioritization.

EPA's work plans have not produced legally-binding risk management obligations on any chemical included. Thus, the number of industrial chemicals prioritized for risk management between the US and EU would likely be *zero* for the foreseeable future, barring more progressive proposals for TSCA reform.

Moreover, there are several processes under REACH where chemicals are scrutinised and prioritised which have no direct equivalent in the US. These are examined below.

4.2 Compliance check of chemicals under REACH

The European Chemicals Agency has a duty to examine at least 5% of all registrations submitted (by 17 February 2014, 47097 submissions had been made public). In the course of these compliance checks, ECHA can ask companies to fill knowledge gaps on chemicals, including through the use of animal testing.[41] ECHA selects dossiers both at random and, increasingly, on the basis of endpoints of concern. The endpoints of concern are usually carcinogenicity, mutagenicity and toxicity for reproduction and environmental persistence, bioaccumulability and toxicity (PBT) as well as other endpoints that influence predictions of environmental fate and exposure routes.[42]

4.3 Substances selected for phase out

The EU has launched a roadmap for the identification of all relevant substances of very high concern. The roadmap foresees the carrying out of an analysis of options for the best risk management measure for all chemicals that are registered under REACH and that fall in the possible hazard categories (CMRs, PBTs and others of equivalent concern, such as EDCs and sensitizers). The worst case estimation made by the Commission is that 440 chemicals would undergo a risk management options analysis. The possible outcomes of this exercise are either the inclusion of the substance in the phase-out list for substitution (Annex XIV) or in a restriction for marketing and use (Annex XVII).

Given the wide divergence between existing lists of EU and US priority substances, the advanced stage and scope of prioritization in the EU, and continued inertia on regulation of new chemicals in the US, efforts to identified shared regulatory priorities between the two parties are unlikely to result in any meaningful efficiency. Indeed, these efforts are far more likely to delay prioritization processes by sharply reducing the number of toxic chemicals that progress to the final stages of risk management.

Table 2: Comparison of chemicals in various lists by the EU and US

	Number of chemicals	Examples of degree of overlap
Prioritization lists		
U.S. EPA TSCA "workplan" (no indication to add additional chemicals)	83 (284 CAS numbers)	
EU CoRAP (chemicals are added regularly)	205 (includes 2014-16 draft)	32 (with TSCA workplan)
EU REACH candidate list of SVHCs (estimated to grow to ~500 by 2020)	151	10 (with TSCA workplan)
Carcinogens identified		
US National Toxicology Program (incl. known and reasonably anticipated)	~212	
EU CLP (known, likely and probable)	1201 (harmonized)	
US IRIS (known, likely and probable since 1986)	130	9 overlap with EU REACH carcinogens
EU REACH candidate list of SVHCs	69	9 overlap with US IRIS
IARC (Group 1, 2A and 2B carcinogens)	464 (113, 66, and 285 respectively)	

5 Classification and Labelling

ACC-CEFIC proposes the development of procedures to identify and resolve differences in classification and labelling for chemical substances and mixtures between the EU and US.[43] Industry proposes: to allow mutual recognition of "each other's compliant product labels;" relabelling after customs clearance; reliance upon a global committee to set a common classification inventory; and to seek to protect trade secrets regarding chemical identity and composition percentages of hazardous substances.

The EU and US are both implementing the United Nations (UN) Globally Harmonized System (GHS) for classification and labelling. The GHS allows a regulatory authority to choose the provisions that are appropriate to its sphere of regulation. This is referred to as the "building block approach."[44] This enables commonality among the international community in hazardous classes and labels (e.g. pictograms) for chemicals and mixtures, but allows flexibility to reflect preferences in the level of protection that governments choose to apply.

Industry proposes to limit the flexibility afforded to the EU and US to inventory chemicals within hazardous classes and to identify relevant hazardous products through mutual recognition of labelling. The classification and labelling of carcinogens provide an example.

In both the US and EU, carcinogens fall into two categories: known or presumed carcinogens; and suspected carcinogens.[45] However, what the two blocs consider carcinogens varies drastically. The US EPA's Integrated Risk Assessment System (IRIS)[46]includes 103 carcinogens. By stark contrast, the EU Regulation on the classification, labelling and packaging of chemicals includes 1201 substances with a harmonised classification as carcinogens (189 known, 826 likely and 188 probable). Further the EU regulation created a compulsory inventory where users of chemicals could submit their self-classification of the hazard properties of chemicals. As a result, the EU database contains 4089 carcinogens. The inventory also includes 2187 mutagens (619 with a harmonised classification) as well as 3904 reproductive toxins (340 with a harmonised classification). Many of these chemicals may represent two or more hazards.

This example illustrates how the ACC-CEFIC proposal would exploit existing differences between the US and EU in identifying chemicals with intrinsic hazards. Allowing mutual recognition (reciprocity) of compliant product labels would mean that products required to be labelled as a carcinogen in the EU but not the US could be exported from the US to the EU without being labelled as a carcinogen, erasing the level of protection established (democratically) by the EU.

Dependence on classification inventory set by a global body ("... the parties shall defer to the UN Global List of Classified Chemicals as a common classification inventory…") could impose a regulatory ceiling. This list does not exist yet. Work on the UN Global List of Classified Chemicals is underway but not yet in effect. The EU, as noted above, has already implemented a system of compulsory notification of the hazard classification of all substances. This system will allow users to discuss their self-classification and further facilitate the increase in harmonised classification of chemicals.[47]

Moreover, at the sub-national level, it could also undercut the application of state initiatives such as California's "Proposition 65," which requires manufacturers to warn the public when knowingly and intentionally exposing anyone to chemicals known to cause cancer, birth defect or reproductive harm. Because products sold in California are also sold throughout the US, the consequences of measures taken by California carry implications at an even larger scale.

6 Emerging scientific issues

The ACC-CEFIC proposal claims that emerging scientific issues present the EU and US with opportunities to align regulations and prevent divergence prior to their enactment. Therefore, in their proposal, ACC-CEFIC suggest that regulatory bodies be required to consult the TSAC on any emerging issues in order to receive the most up-to-date information possible.

It should be noted that the European Union has emerged as a global leader in acknowledging and beginning to address urgent issues in its chemicals management regulation, such as endocrine (hormone) disrupting chemicals, nanotechnologies, and the risks presented by chemical mixtures. Adding another regulatory consultation and co-ordination layer would delay that progress whilst alignment of regulation was considered. Here, again, efforts to confront emerging threats at the state level in the United States could be similarly impeded. Endocrine disrupting chemicals (EDCs) and nanomaterials are discussed below.

6.1 Endocrine disrupting chemicals

The EU has begun to regulate the use of chemicals with endocrine disrupting properties. Under EU regulations for pesticides, for example, it is not foreseen that endocrine disrupting chemicals could be approved for use. Under REACH, substances with endocrine disrupting properties that give rise to a substantial level of concern for people or the environment may be included in the candidate list as SVHCs, and may be prioritised for substitution through the Authorization process.

Hazard-based criteria for identifying endocrine disrupting chemicals will be defined pursuant to the pesticides and biocides regulations. Given the likelihood of exposure to these chemicals following pesticide and biocidal uses, the two product-specific regulations foresee the phase-out of endocrine disrupting substances on the basis of their intrinsic properties, with limited socioeconomic-based exceptions. The potential economic impact of these criteria on the chemical industry has triggered strong opposition to hazard-based criteria for endocrine disruptors. Industry opposes the use of hazard-based criteria to determine safe levels of exposure as "non-scientific" despite emerging and credible evidence of the harms they pose. Indeed, and industry rhetoric notwithstanding, the EU law is based on weight of evidence of all scientific knowledge available.

Weak safety standards in the US have allowed hundreds of chemicals with endocrine disrupting properties onto the market . Through authority created by amendments to three major US environmental statutes in 1996, EPA is developing methodologies for the screening and testing of pesticides and other environmental contaminants for their potential to disrupt the endocrine system.[48] EPA has proposed a two-tiered screening and testing process, in which EPA undertakes a hazard assessment, exposure assessment and, ultimately, a risk assessment to determine potential harm of a chemical with the likelihood that someone or something will be exposed. EPA estimated the potential “universe of chemicals” that require screening is up to approximately 9,700 (note over 80,000 substances are listed in the US TSCA inventory of industrial chemicals alone); issued the first requests for data in 2009 for 67 chemicals; and is

prioritizing additional chemicals for screening. As of yet, no risk management steps have been taken by EPA.

6.2 Nanomaterials

Nanomaterials have unique physical and chemical properties that make them distinct 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.

Recently-approved EU laws have recognized the right for consumers to know about the content of nanomaterials in cosmetics and in food. In October 2012 and February 2013, the Commission Communication on the Second Regulatory Review on Nanomaterials and the REACH Review both concluded that REACH and CLP should constitute the risk management framework for nanomaterials when they occur as substances or in mixtures.[49] Therefore, nanomaterials fulfilling the criteria for classification as hazardous under Regulation 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures must be classified and labelled. Additionally, under the biocidal products regulation, if a product contains nanomaterials, the risk from the substance in the nanoform must be assessed separately. Further, the Regulation establishes a definition of nanomaterial.

In the United States, nanomaterials that are regarded as chemical substances are currently regulated on a case by case basis under TSCA's "unreasonable risk" standard. In 2010, the EPA submitted a draft proposal to the White House Office of Management and Budget (OMB) for a combined nanomaterial information collection rule and nanomaterial significant new use rule that would apply to any new use of a nanomaterial, with an exception for pre-existing commercial applications that would be grandfathered in. The OMB has yet to issue a response.

EDCs and nanomaterials illustrate yet another example of areas where legislative processes, although slow and not comprehensive, are well underway in the EU, but equivalent action in the United States either lags far behind, or is altogether lacking. Although cooperation in these areas is desirable, especially in relation to definitions, at the end of the day, approaches to risk management are so divergent that it would be unlikely to accelerate—or even advance—needed regulatory action to tackle these relatively new risks.

7 Mutual recognition of notifications and registrations

ACC-CEFIC propose mutual acceptance of notifications and registrations in the US and EU respectively, to allow companies to use either the REACH registration process or the TSCA pre-manufacture notice (PMN) process to gain access to either market for an unspecified period of time.[50] This would erase a fundamental pillar of REACH for the most widely used chemicals: no data, no market.

Under US law, chemical manufacturers are not required to submit health and safety information under TSCA unless that information is already available. Thus, the great majority of PMNs have virtually no data to conduct even a basic risk assessment. For example, according to EPA, 85% of PMNs contain no health data, and more than 95% of PMNs contain no eco-toxicity data.[51]

The EU seeks to ensure the safety of chemicals for their intended purpose by requiring a minimum data set about industrial chemicals. Minimum data requirements are tiered based on production volume.[52] For those manufactured in quantities above1 ton/year, a minimum data set is required. The minimum data set is the most significant distinction between the US "notification" and EU "registration" systems.

Thus, allowing the interchangeability of PMNs with REACH registrations would undermine the principle of "no data, no market," making it difficult to regulate chemicals by limiting data flows to regulators, and thereby undermining EU's principle that it is the responsibility of whoever placed the chemical on the market to demonstrate its safety. This system would create a competitive advantage to notify all new chemicals in the US, thereby bypassing REACH registration requirements, which are more burdensome in requesting safety data. Product makers and retailers value this data in making materials selection decisions that protect their workers, shareholders, customers, and brand name.

8 Information sharing and protection of confidential business information (CBI)

With regards to information sharing, ACC-CEFIC propose to develop new rules regarding how governments access information, what types of information is eligible to be CBI, and for how long it can be protected. These proposals threaten to undermine, conflict and disregard policies in favour of the right-to-know about chemical-related risks and existing EU obligations under the Aarhus Convention.

8.1 Information sharing

Information sharing is an essential condition to achieve minimisation of animal testing and reduce cost of hazard assessment for companies on both sides of the Atlantic and beyond. However, obstacles exist in obtaining information on substances when the data is owned by a party who could refuse disclosure of the information contained in a study.[53]

Under REACH, much of the information on chemicals will be made progressively available through the web portal of ECHA. REACH foresees the possibility of confidentiality claims only in relation to a limited set of data (precise use, composition of a mixture and precise tonnage).[54]

Under the OECD's Decision on Mutual Acceptance of Data,[55] test data that is generated in any OECD Member State in accordance with the OECD Test Guidelines and Principles of Good

Laboratory Practice (GLP) will be accepted by other OECD Member States for the purpose of environmental and human health assessments.

It is worth bearing in mind the imbalance of information available to EU versus US regulators. REACH is generating, and will continue to generate, substantial information for regulatory decisions on chemicals. Without such data, EPA cannot exercise its authority to ban or restrict the use of an industrial chemical under TSCA.

The US Government Accountability Office (GAO) recommended in June 2005 that EPA strengthen its ability to regulate harmful chemicals under TSCA by, for example, promulgating a rule requiring that companies submit copies to EPA of any health and safety studies, as well as other information concerning the environmental and health effects of chemicals that they submit to foreign governments.[56] EPA is thus now seeking from industry the data that US companies may have submitted in the context of their REACH registration but have decided not to share with the EPA; another indicator of unwillingness on the part of the chemical industry to data sharing and to providing the right to know to the public. Under Section 11(c) of TSCA, EPA has the authority to require the production of reports, papers, documents, answers to questions, and other information that EPA deems necessary to carry out its functions.

8.2 Confidential business information

ACC-CEFIC maintains that trade secrets and CBI are critical assets and key indicators of competitiveness and innovation. Therefore, ACC-CEFIC proposes the development of well-defined, mutually agreed-upon criteria for defining the parameters of confidential business information and the timing for claims so as to achieve a balance between transparency and protection of information. Industry also aims for protective safeguards of CBI that is submitted to fulfil regulatory requirements, ensuring respect for ownership rights, exclusive use, and compensation, and ensuring the protection of CBI in the customs process.[57]

ACC-CEFIC further states that the US and EU authorities should have the authority to share CBI with one another for the purpose of assessing the safety of chemicals; but only if the receiving authority can demonstrate equivalent procedural safeguards to protect the rights of CBI claimants as well as the government disclosing the CBI.

However, the proposal from ACC-CEFIC demonstrates a complete disregard for the EU's international commitment under the Aarhus Convention, which ECHA has to take into account when implementing its information dissemination obligations.

The disclosure of data under REACH and the REACH principle of the "right to know" fall under general principles of access to environmental information that are foreseen as a consequence of the EU being a party to the Aarhus Convention. These legally binding provisions establish a general presumption that environmental information should be publicly available, with only a limited number of exceptions which are narrowly construed. It should be noted that, under the Aarhus Convention, disclosure of information on "emissions into the environment" cannot be refused on the basis of commercial confidentiality. A recent landmark decision of the EU Court

of Justice found that the exact composition of a pesticide, including its impurities, had to be disclosed as it was held to be information relating to emissions into the environment "even if such disclosure is liable to undermine the protection of the commercial interests of a particular natural or legal person, including that person's intellectual property."[58]

As the jurisprudence of the ECJ on the disclosure of information on chemicals increases in quantity and quality, the concept of CBI in relation to environmental information and information on chemicals will be adapted. Industry proposals are clearly seeking to neutralise and frustrate the increasing calls for full disclosure of information about the toxic chemicals placed on the market.

It should be observed that the abuse of claiming confidentiality of data under TSCA is generally regarded as one of the major flaws with the law, including its failure to enable a transition to safer chemicals over the past 38 years. An estimated 16,000 chemical identities are covered by CBI under TSCA. The EPA is now challenging industry to resubmit their claims in order to gain more transparency[59]. This will take years, and the effectiveness of this challenge is by no means certain. The US is not a party to the Aarhus Convention and so the bottlenecks created in the US cannot be unblocked by this route.

Any attempt to develop common definitions of what constitutes CBI must be preempted by the obligations of the EU which derive from its being a party of the Aarhus Convention. Thus any negotiation on this issue with a party that does not recognize the fundamental principles of the Aarhus Convention would be open to legal challenge.

Conclusion

The proposals by ACC and CEFIC aim at nothing less than manipulating the pace and direction of chemicals regulation in the EU and US through the inclusion of specific language and content in TTIP; language crafted to benefit the chemical industry, not public health or the environment.

These proposals would delay the development of stronger rules for hazardous chemicals in the US and EU, and undermine democratic principles that underlie two of the world's largest economies. The ACC-CEFIC proposal will not add any benefit from the implementation of many of the cooperation actions suggested. Many activities have been carried out by the OECD on test methods for determining hazardous properties of chemicals; and on the quality, reliability, and mutual acceptance of data. Scientific cooperation would simply delay, or even prevent, risk management decisions from being taken. Mutual recognition of notification of new chemicals in the US and registration in the EU would eliminate minimum data requirements about the safety of chemicals on the market, allowing companies to use weaker US requirements to gain access to the EU. Common prioritisation of chemicals in the regulatory process would reduce the number of chemicals that would otherwise be subject to risk management decisions, and erode existing decisions on prioritization by European authorities.

From whatever perspective we look at this proposal, there is not a single idea in this paper that could increase the efficiency of trade among the two blocs or reduce costs to governments without sacrificing stricter controls for toxic chemicals. The proposal would, in fact, create additional bureaucratic layers that would increase the costs of government to taxpayers. Moreover, externalized costs to society would perpetuate and increase, due to health care and remediation, from the delays in reducing the emission of toxics substances into the environment. It is possible that negotiators would not embrace all of the chemical industry's proposals, as it is in many ways too prescriptive and would undermine the rule of law. However, the negotiators have been open to industry proposals from the start of the negotiations and we have a legitimate concern that there will be bargaining in favour of the chemical industry. The EU has stated its commitment to build by 2018 a strategy for a non toxic environment that is conducive to public health, innovation and the development of sustainable substitutes. The US has no such objective.

Given the irreconcilable differences in chemicals regulation between the two parties and the audacious nature of chemical industry proposals that appear carefully crafted to exploit these differences, rather than reduce them in a way that serves the broader public good, we call for the negotiators to clearly reject all proposals from the chemicals industry that do not seek to eliminate the production and use of hazardous chemicals. With a discussion that is transparent, open, and truly aims to improve the well-being of people in the US and EU, a trans-Atlantic dialog could be started to achieve regulatory convergence in the chemical sector.

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Annex 1

ACC and CEFIC Joint Proposal – Enhancing EU-US Chemical Regulatory Cooperation Under TTIP: www.clientearth.org/external-resources/ttip-information/140310-ttip-regulatory-cooperation-joint-acc-cefic-proposal-12102013.pdf

Annex 2

European Commission Position Paper on Regulatory Cooperation: www.clientearth.org/external-resources/ttip-information/140310-eu-position-paper-on-regulatory-cooperation.pdf

1 Reducing Transatlantic Barriers to Trade and Investment: An Economic Assessment, Prepared under implementing Framework Contract TRADE10/A2/A16 at 16, 30–32 (Mar. 2013), available at pgs 16, 30-32 http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf

2 See USTR 2013 Report on Technical Barriers to Trade, available at http://www.ustr.gov/sites/default/files/2013%20TBT.pdf; The Chemical Industry, The Bush Administration, and European Efforts to Regulate Chemicals, House Committee on Government Reform, report prepared for Chairman Henry Waxman,110th Congress (2004) [hereinafter Chemical Report to Henry Waxman] available at http://oversightarchive.waxman.house.gov/story.asp?ID=427; Soc'y of Chem. Mfrs. & Affiliates, "REACh is Largest EU Trade Barrier for U.S. Chemical Manufacturing SMEs, SOCMA Testifies" (Nov. 20, 2013), available at http://www.socma.com/pressRoom/index.cfm?subSec=3&sub=71&articleID=4382

3 UN Environment Program (UNEP), Global Chemicals Outlook (2012).

4 See Joint EEA-JRC Report No 5/2013, Report EUR 25933, Environment and human health, at page 21, available at http://www.eea.europa.eu/publications/environment-and-human-health.

5 UN Environment Program (UNEP), Cost of Inaction Report (2012).

6 Report of the French National Assembly Commission on European Affairs on the European Strategy for Endocrine Disrupting Chemicals, 101 (Feb. 25, 2014) ("Considérant que l'innovation s'en trouvera stimulée, puisque cela incitera à la recherche et au développement de nouvelles substances inoffensives, susceptibles d'être substituées à celles présentant un danger"), available at: http://www.assemblee-nationale.fr/14/pdf/europe/rap-info/i1828.pdf. CIEL, Driving Innovation: How Stronger Laws Enable Safer Chemical to Enter the Market (Feb. 2013), available at: http://ciel.org/Publications/Innovation_Chemical_Feb2013.pdf .

7 See e.g. Stockholm Convention on Persistent Organic Pollutants, preamble. See also, SAICM, Chemicals in Products Emerging Policy Issue, available at: http://www.saicm.org/index.php?option=com_content&view=article&id=454&Itemid=691

8 UNEP, Global Chemicals Outlook (2012); and OECD, Environment Outlook to 2050: The Consequences of Inaction (2012).

9 Swedish Chemical Inspectorate (KEMI), The Influence of Legislation on the Location of the Chemical Industry (2013).

10 See e.g. Corporate Europe Observatory, Profiting from Injustice (2012); See also Friends of the Earth Europe, The TTIP of the anti -democracy iceberg: The risks of including investor-to-state dispute settlement in transatlantic trade talks (October 2013); and Public Citizen, Investor-State System (webpage), available at: http://www.citizen.org/investorcases

11 ACC-Cefic Joint Proposal: Enhancing U.S.-E.U. Regulatory Cooperation under TTIP [hereinafter ACC-Cefic Joint Proposal] (see Annex 1). We received a copy of this document from an unknown source through Corporate Europe Observatory. Numerous sources have confirmed that the chemical industry's proposal was discussed by negotiators during the December 2013 meetings, reinforcing concerns over the very limited transparency of these and other trade negotiations, as well as bias toward economic interests.

12 USTR, 2013 Report on Technical Barriers to Trade, supra note 2; Chemical Report for Henry Waxman, supra note 2; SOCMA press release, supra note 2.

13 ACC-Cefic, supra note 12

14 The proposal does not define "chemical sector," and thus could include formulators, distributors and downstream users. "Chemical" is defined as "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any intentional additive, but excluding any solvent which may be separated without affecting the stability or changing its composition. See ACC-Cefic Joint Proposal, supra note 3,proposal at 15.

15 Karel De Gucht, European Trade Commissioner European Commission,Speech - Trans-Atlantic Trade and Investment Partnership (TTIP) – Solving the Regulatory Puzzle, Karel De Gucht European Trade Commissioner European Commission - SPEECH/13/801 (October 10, /10/2013).

16 Delegated acts in the EU are when the legislator delegates the power to adopt acts amending non essential elements of a legislative act to the Commission, pursuant to the provisions created by the Lisbon Treaty.

17 The EU proposes that the US legislators and/or regulators (1) respond to EU proposals and comments; (2) provide periodic reviews of upcoming legislation; (3) maintain continuous dialogue with regulators across the Atlantic throughout the rulemaking process (in the US, the entities in charge of this function would be the US Congress, the Office of Management and Budget (OMB) and the Office of Legislative Information (OLI)); and (4) fully disclose and explain all impact assessment/cost-benefit analyses to the EU Commission. This final point also risks the potential prioritization of trade liberalization at the expense of environmental and social goals through cost-benefit analysis (i.e. impact assessments)

18 ACC-Cefic Joint Proposal, supra note 12

19 ACC-Cefic Joint Proposal, supra note 12

20 ACC-Cefic Joint Proposal, supra note 12 at 7.

21 Rio declaration on Environment and Development,, principle 15 (1992),

22 For further reference see EEA Report No. 1/2013, Late lessons from early warnings: science, precaution and innovation, available at http://www.eea.europa.eu/publications/late-lessons-2.

23 See e.g. US GAO, Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System, 28–29 (2009) ("EPA management's decision in some cases to suspend ongoing IRIS assessments while waiting for additional scientific studies to be completed has contributed to EPA's lack of productivity … Another management decision that has delayed the completion of IRIS assessments is to incorporate comprehensive uncertainty analysis into the IRIS assessments).

24 NRDC, The Delay Game, How the Chemical Industry Ducks Regulation of the Most Toxic Substances, at 2 (2011) [hereinafter NRDC, The Delay Game].

25 Id.;25 NRDC, The Delay Game; The recurring failure of EPA to complete its IRIS assessments to set new legal limits on chemicals is so severe that the independent investigative arm of the US Congress, the GAO, investigated.

26 WHO, IARC, NTP. Trichloroethylene is identified in the EU as a substance of very high concern and, unless authorised for specific uses, it cannot be used in the

EU from 21 April 2016.

27 NRDC, The Delay Game, supra note 22, at 6–6-8. (2011). Other acknowledged carcinogens include formaldehyde (thirteen years), styrene (fifteen years), and dioxin, already restricted by over 170 countries under a global treaty (to which the U.S. is not a party), which took fourteen years.

28 ACC-Cefic Joint Proposal, supra note 3,CEFIC at 8 ("...Identify and consider the impact on Trans-Atlantic and international trade; Identify the potentially effective and reasonably feasible regulatory options likely to achieve the policy objective; [and] Identify, where appropriate, the grounds for concluding that the selected alternatives achieves the policy objectives in a way that maximizes net benefits, including qualitative benefits, while also considering distributional impact…").…")

29 US GAO, Chemical Regulation: Observations on the Toxic Substances Control Act and EPA Implementation, at 8 (2013) [hereinafter US GAO, Observations on TSCA and EPA Implementation], available at http://www.gao.gov/assets/660/655202.pdf

30 Corrosion Proof Fittings v. EPA, 947 F.2d 1201 (5th Cir. 1991). 30

31 US GAO, Observations on TSCA and EPA Implementation, supra note 27, at 9. The ban in question was for31 hexavalent chromium, a known human carcinogen widely used in industrial cooling towers.

32 Id.32 US GAO, Observations on the Toxic Substances Control Act and EPA Implementation, 9 (2013)

33 I.e. These substances need to be authorized for specific uses after inclusion in Annex XIV, and having the properties listed in Article 57 of REACH. ..

34 Persistent, bioaccumulative and toxic.

35 Very persistent and very bioaccumulative.

36 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.

37 Congressional Research Service (CRS), Chemical Regulation in the European Union (EU): Registration, Evaluation, and Authorization of Chemicals, CRS Report RL34118 at 17 (Oct. 23, 2013), available at http://www.fas.org/sgp/crs/row/RS22673.pdf.37 CRS Report RL34118, supra note 7, at 17.

38 Under REACH, only chemicals placed on the market over one metric tonne have to be registered and for chemicals produced between 1 and 10 tonnes only a simplified set of data must be produced in the registration dossier.

39 OECD Test Guidelines (webpage), available at: http://www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicals.htm

40 US EPA, TSCA Workplan Chemicals, available at http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html. 40 http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html

41 Compliance checks cover also the proposed risk management measures and the preparation of the chemicals safety report.

42 ECHA, Evaulation under REACH Progress Report 2013 at 17, available at http://echa.europa.eu/documents/10162/13628/evaluation_report_2013_en.pdf. 42 ECHA progress report on evaluation 2013, page 17.

43 EU Regulation (EC) No 1272/2008 on the classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (16 Dec. 2008) [hereinafter EU (CLP Regulation];) and U.S. OSHA Hazard Communication Standard 29 CFR Part 1910.1200 final rule (HCS 2012).)

44 OSHA GHS Final Rule Guidancefinal rule guidance, at 21, available at https://www.osha.gov/dsg/hazcom/GHSfinal-rule.pdf

45 Id.OSHA GHS final rule guidance, at 22; https://www.osha.gov/dsg/hazcom/GHSfinal-rule.pdf; EU CLP Regulation, supra note 40, at §sect. 3.6.

46 Those determined to be known, likely, probable carcinogens since 1986.

47 See ECHA,ECHA's Multi Annual Work Programme 2014–-2018 at, page 24, available at http://echa.europa.eu/documents/10162/13608/final_mb_38_2013_mawp_2014-2018_en.pdf. http://echa.europa.eu/documents/10162/13608/final_mb_38_2013_mawp_2014-2018_en.pdf

48 EPA, Endocrine Disruptor Screening Program (webpage), available at: http://www.epa.gov/endo/index.htm

49 European Commission, Second Regulatory Review on Nanomaterials, COM(2012) 572 final (Oct. 3, 2012), available at 49 http://eur-lexeurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0572:FIN:EN:PDF; European Commission, General Report on REACH, COM(2013) 49 final (Feb. 5, 2013), available at ; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0049:FIN:EN:PDF.

50 ACC-Cefic Joint Proposal, supra note 12, at 19.

51 US EPA, Overview: Office of Pollution Prevention and Toxics ProgramsOVERVIEW:OFFICE OF POLLUTION PREVENTION AND TOXICS PROGRAMS, 8 (Jan. 2007), available at : http://www.epa.gov/oppt/pubs/oppt101c2.pdf; and US EPA, Q&A New chemicals program, 1-55 (2004), available at: http://www.epa.gov/opptintr/newchems/pubs/qanda-newchems.pdf.

52 European Commission Regulation 1907/2006, Registration, Evaluation, Authorisation and Restriction of Chemicals, Annexes VII-VIII, 2006 O.J. (L 396) 1 (EC) [hereinafter REACH], available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:EN:PDF52 REACH, Annexes VII-VIII

53 In order to be able to refer to a study report, the registrant must be in possession of a permission to refer to the study (e.g. a letter of access). See ECHA,ECHA's Guidance on data sharing, Version 2.0 (2012) (ECHA-2012-G-01-EN), available at https://echa.europa.eu/documents/10162/13631/guidance_on_data_sharing_en.pdf.).

54 REACH, supra note 49, art. 118.

55 OECD, Decision of the Council concerning the Mutual Acceptance of Data (MAD) in the Assessment of Chemicals C(81)30/FINAL (12 May 1981), available at http://acts.oecd.org/Instruments/ShowInstrumentView.aspx?InstrumentID=263&InstrumentPID=263&Lang=en&Book=False55 REFERENCE TO AGREEMENT

56 US 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. June 13, 2005). According to congressional testimony in 2013, GAO states that "EPA did not disagree with our 2005 recommendations regarding obtaining health and safety studies and other information that companies submit to foreign governments and requiring companies to reassert confidentiality claims, but it provided substantive comments and has not fully implemented these recommendations.";.", US GAO, Observations on TSCA the Toxic Substances Control Act and EPA Implementation, supra note 27, at 9.9 (2013)

57 ACC-Cefic Joint Proposal, supra note 12,CEFIC at 4–, 5.

58

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