July 2014

Toward a Toxic Partnership

A critique of the EU position on chemicals under the Trans-Atlantic Trade and Investment Partnership (TTIP) Agreement with the US

In May 2014, the European Commission disclosed to the public certain elements of their vision for "regulatory cooperation" between the EU and US on industrial chemicals under TTIP.[i]

The Commission position paper broadly describes a sectoral annex (or chapter) on "chemicals", with brief mention of mutual recognition and harmonization under separate sectoral annexes for cosmetics and textiles, respectively. The proposal from the Commission draws from the chemical industry's proposals for TTIP. When read together with the leaked position paper of the EU for the horizontal regulatory coherence chapter[ii], and leaked proposals by the American Chemistry Council (ACC) and European Chemical Industry Council (Cefic)[iii], it is apparent that none of the chemical industry's proposals are, in principle, excluded.

In particular, the EU paper explicitly incorporates five of eight proposals from industry's suggested chemicals chapter. For the remaining three suggestions, the effect of the functioning of a regulatory cooperation council (or "institutional framework"), as well as the aim of having the TTIP as a "living agreement", would open the door to the adoption of the remaining proposals from the chemical industry in the future.

Like the chemical industry's proposals from which they originate, the EU's vision for TTIP in the chemicals sector would obstruct efforts to promote the substitution of harmful substances with safer alternatives, enshrined in EU chemical laws over the last decade. These proposals would:

- Freeze progress in regulating toxic chemicals, including by US states;
- 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.

Although the Commission disclosed some elements of its TTIP proposals, , several key sections of TTIP relating to the chemicals sector were either not disclosed or referenced only vaguely. This makes a complete assessment of the Commission's positions impossible (see Box 1).

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[i] European Commission, EU position on chemicals (May 2014), available at: http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152468.pdf

[ii] EU position paper on Regulatory Coherence (Dec. 2013), available at: http://corporateeurope.org/trade/2013/12/regulation-none-our-business

[iii] ACC-Cefic Joint Proposal: Enhancing EU-US Regulatory Cooperation under TTIP (Dec. 2013), available at: http://ciel.org/Publications/CH_Pro.pdf

Box 1: Known Unknowns: What the Commission did not mention or describe in detail in its "position" about TTIP and the chemicals sector.

(1) Trans-Atlantic institution for "Regulatory Coherence/Cooperation." This is one of the most concerning aspects of TTIP due to its potentially significant chilling effect on the regulation of toxic chemicals, greenhouse gases, and other public health and environmental threats. Proposals call for nearly all legislative and regulatory measures to be assessed for their effect on international trade, and protective measures limited to the least trade restrictive option. In addition, the EU and US would create additional avenues for foreign government and industry to question and delay stronger measures.

(2) Investment. Investor-State Dispute Settlement (ISDS) provisions of trade and investment agreements have enabled chemical regulations to be challenged by corporations demanding either revision or compensation for lost profits from stronger public health and environmental measures, another key source of TTIP's chilling effect.

(3) Pesticides. It is rumoured that there will be a sectoral annex in TTIP on pesticides. Industry continues to insist that the EU change its laws, abandon the precautionary approach by ending the prohibition on marketing pesticides with hormone (endocrine) disrupting properties and other intrinsic hazards, and raise the amount of pesticide residues allowed on imported agricultural goods.

(4) Technical Barriers to Trade (TBT) and Sanitary Phytosanitary (SPS) Measures. The US and industry continue to argue that EU chemical laws violate to WTO TBT and SPS rules. Negotiators state they intend to go beyond WTO standards, but have not given adequate information to evaluate what the implications would be for environmental measures on both sides of the Atlantic, including the EU's stronger chemical laws.

The United States (US) has been even less forthcoming than the EU regarding its objectives for TTIP. The only aspects of the US government position disclosed publicly are: (1) steadfast disagreement with the EU's ongoing elevation of standards for protecting the public from toxic chemicals, including the presumption against the use of carcinogens, hormone (endocrine) disrupting chemicals, and other chemicals of concern; and (2) distress that the continued elevation of European standards will reduce the ability of US industry to export food and other products containing toxic chemicals to the EU.

The Commission position paper on chemicals proposes the following objectives for TTIP:

(1) Mutual consultation in drawing up lists of priority chemicals and cooperation in the development of assessment methodologies;

(2) Promoting alignment (harmonization) in the classification and labelling of chemicals;

(3) Efforts to reduce regulatory differences on hormone (endocrine) disrupting chemicals, nanomaterials, and chemical mixtures (i.e. “new and emerging” issues);

(4) Agreeing whether, when and how information about chemical safety is exchanged between regulators, including what should be considered confidential business information (CBI).

Each idea presented raises serious concerns. In particular, the idea of joint efforts on new and emerging issues is a threat to long-overdue regulation of endocrine disrupting chemicals (EDCs) and measures to address the risks of nanomaterials. This represents a major concession to the US trade negotiators and industry who have attacked the EU regarding the prospect of stronger measures on these urgent issues. Further, the position papers on textiles and cosmetics open the door to mutual recognition and harmonisation, despite public statements by EU negotiators that this was not possible for chemicals.

Below we summarize our conclusions in relation to each of the proposals by the European Commission. These conclusions are based on our earlier analysis of similar proposals by the chemical industry.[iv]

[iv] CIEL-ClientEarth, Toxic Partnership: A critique of the ACC-Cefic proposal for trans-Atlantic cooperation on chemicals (March 2014), available at: http://ciel.org/Publications/ToxicPartnership_Mar2014.pdf

1. Cooperation in prioritising chemicals for assessment and assessment methodologies:

- Cooperation in prioritizing chemicals for assessment risks reducing or delaying the number of chemicals undergoing risk assessment. These changes would subsequently reduce the number of chemicals of concern subject to risk management.

- There is very little overlap between existing lists of chemicals for assessment between the US and EU. The EU and US have already allocated responsibilities and are not duplicating efforts. For example, only ten chemicals overlap out of a total of over 230 chemicals listed in certain priority lists of the US and EU.[v] Thus, there is very little regulatory efficiency to be gained because the US and EU are not duplicating efforts.

- The US does not have a rigorous prioritization process in place for industrial chemicals at the national level. Prioritization schemes do exist at the state level in the US. The selection of chemicals for EPA's Chemical Management Plans (including chemical "action plans" and "work plans") is driven in large part by progress indentifying, assessing and managing certain chemicals of concern outside the US (see e.g. Table 1).[vi]

- The "Report on Carcinogens" of the US National Toxicology Program is not a prioritization scheme; rather it "is a Congressionally mandated document that identifies and discusses ... [substances] ... that may pose a hazard to human health by virtue of their carcinogenicity."[vii] Unlike EU law, carcinogens are not subject to authorization or phase-out under relevant US chemical laws.

- The EU's Community Rolling Action Plan (CoRAP) list of substances for evaluation is not comparable to any aspect of US TSCA. Through the CoRAP, the EU seeks to generate additional information in specific areas of concern for chemicals that have already been assessed for risk as a condition of their registration under REACH. Thus, the only foreseeable impact of the proposed mechanisms under TTIP, would be to give increased influence to US entities in the review and revision process of CoRAP, which is updated and populated with around 40 additional substances for evaluation every year.

- The EU proposal also includes cooperation in implementing the Substances of Very High Concern (SVHCs) Roadmap to 2020 which aims at having all relevant currently

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[v] *Id.* at 17 (Table 2). Comparing other EU and US priority lists—e.g. CoRAP with workplan chemicals—produces similar results. *Id.*

[vi] See EPA, Existing Chemical Action Plans (last accessed July 6, 2014), available at: http://www.epa.gov/opptintr/existingchemicals/pubs/ecactionpln.html#posted ("The initial chemicals selected were chosen on the basis of multiple factors, including, among others: … Chemicals subject to review and potential action in international forums").

[vii] NTP Report on Carcinogens Review Process (last accessed June 26, 2014), available at: http://ntp.niehs.nih.gov/?objectid=FA925F34-F1F6-975E-775C81773747D452

known SVHCs included in the candidate list by 2020. Again, under US law there is no similar process. Cooperation would allow the US to intervene in or influence the "risk management options" analysis carried out by EU Member States, which is designed to identify the best risk management measure for hazardous chemicals.

- Under REACH, all processes for prioritisation, hazard identification and risk management of chemicals are carried out transparently either through open public consultations or through stakeholder consultations (see Annex I for a detailed list). Industry and foreign governments are already able to participate in these EU consultations; thus, there is no need or added value to creating a process for increased (or even separate) US participation in EU processes.

- Cooperation on risk assessment methodologies would likely create additional avenues for industry and US government allies to pressure the EU to weaken its current, more protective approach that focuses on carcinogenicity, endocrine disruption and other intrinsic hazards. There is limited cooperation between ECHA and EPA on methods for assessment/evaluation. Additional mechanisms to help intensify cooperation would also make it more difficult to "integrat[e] new scientific developments," one of the suggested objectives of cooperation in this area.

Table 1: **Impact of EU and global processes on US "action plan" chemicals.**

EPA "action plan chemicals" – listed in 2011	Example of action outside of the US
1. Bisphenol A	French and Danish measures in 2010; EU Directive banning use in baby bottles in 2011; EU harmonised classification and labelling as toxic for reproduction in 2013
2. Benzidine Dyes	EU Directive in 2003 prohibiting the production and sale of certain articles containing benzidine, following several Member State initiatives beginning in 1994
3. Hexabromocyclododecane (HBCD)	EU REACH Candidate List since 2008, Authorisation List since 2011; Global restriction under Stockholm Convention on POPs in 2013
4. Long Chain Perfluorinated Chemicals (PFCs)	Global restriction on several uses of PFOA/PFOS under Stockholm Convention on POPs in 2009
5. Methylene Diphenyl Diisocyanate (MDI) and Related Compounds	EU REACH (Restriction in 2008)
6. Nonylphenol (NP) and Nonylphenol Ethoxylates (NPEs)	Restricted from several uses in EU since 2003
7. Phthalates (includes eight phthalates)	EU Decision restricting phthalates in toys and childcare articles (1999); EU REACH (several in Candidate List in 2008, Authorization List in 2011 and Restriction in 2009)
8. Polybrominated Diphenyl Ethers (includes Penta, Octa, and Decabromodiphenyl Ethers) (PBDEs)	Global restriction under Stockholm Convention for Penta and Octa in 2009; Proposal for global phase out for Deca in 2013 under Stockholm Convention; EU REACH Candidate list (Deca) in 2012.
9. Short-Chain Chlorinated Paraffins (SCCPs) and Other Chlorinated Paraffins	Under consideration for global restriction under Stockholm Convention since 2006; EU REACH (Candidate List 2008)
10. Toluene Diisocyanate (TDI) and Related Compounds	

2. Promoting alignment in classification and labelling:

- The EU is implementing the Global Harmonised System (GHS) for the Classification and Labelling of Chemicals through Regulation 1272/2008 (the CLP Regulation). In the US, the Occupational Safety and Health Administration (OSHA) has implemented parts of the GHS for chemicals used at the workplace, but not US EPA or other relevant US agencies.[viii] There is no need for the US to conclude a trade agreement in order to implement GHS; US EPA and other US agencies could simply implement the GHS at a minimum, and retain what they have that is better than the GHS agreement.

- However, pre-emption of states in the US is a serious concern with implementation of GHS. An attempt to align classification and labelling could result in lower protection in states that have implemented enhanced protective requirements for workers and citizens. For example, California has exceeded both national and GHS requirements for protecting workers from toxic chemicals.

- The suggested reliance on a multilateral list of chemical classification that has not yet been established is also of great risk. Multilateral negotiations are complex. Negotiated outcomes may take years or, in some cases, more than a decade, due in large part to the infrequency of meetings and the challenge of reaching consensus or a super-majority amongst nearly 200 sovereign countries. Our previous Toxic Partnership report illustrates the different outcomes between EU and US, with respect to the classification of carcinogens and other chemicals of high concern.

- Finally, the proposal suggests the creation of a mechanism for mutual consultation and involvement in processes for harmonised classification and labelling. Additional mechanisms are not needed in the EU as decisions on classification and labelling undergo public consultations where all contributions are taken into account (see Annex I). Whereas, in the US, a harmonised classification system is not in place.

3. Co-operation on new and emerging issues:

- Endocrine disruptors (EDCs) are a class of chemicals recognised as a global threat by the World Health Organisation, the United Nations Environment Programme and other international organizations. Drawing upon industry's concerns, and continuing a long pattern of using trade to argue against the development of stronger chemical laws in the EU, the US Trade Representative (USTR) has highlighted the prospect of stronger measures in the EU for EDCs as potential trade barriers.[ix] These trade-based arguments are not founded on restricting the flow of goods or services, but

[viii] OSHA final rule, Docket No. OSHA-H022K-2006-0062, available at: https://www.osha.gov/dsg/hazcom/GHSfinal-rule.pdf.

[ix] USTR, 2014 Report on Technical Barriers to Trade, 68-70 (2014), available at: http://www.ustr.gov/sites/default/files/2014%20TBT%20Report.pdf

rather on the costs to businesses from public interest regulation, without valuing the cost of inaction on EDCs and other chemicals of concern.[x]

- Extensive lobbying by industry and scientists with industry-ties and, perhaps, the threat that strong criteria over EDCs would jeopardize TTIP, appear already to have had an adverse effect on the decision making process on the EDC criteria. Under existing EU laws, pesticides with endocrine disrupting properties will not be approved in the future. However, in a recent proposal by the European Commission, two of three options contain approaches to risk-assessment and socio-economic elements similar to weaker US laws.[xi] This approach is in marked contrast to what is required under EU legislation.[xii] Due to the strong difference in views between the EU and the US on how to assess the hazards and risks of endocrine disruptors, regulatory cooperation aiming at avoiding trade irritants would weaken and delay the development of protective laws.

- USTR has also taken on board industry's concerns regarding the development of laws in the EU and by EU Member States to address the unique risks presented by nanomaterials.[xiii] The EU has initiated a review and adaptation of its regulatory framework. The Cosmetics Regulation, Biocidal Products Regulation and the Regulation on the Provision of Food Information to Consumers now include nano-specific provisions, such as obligations for labelling, pre-market authorization and specific testing requirements. Several EU Member States have developed or are in the process of developing registers for nanomaterials and nano-containing products. The EU Commission is also considering an EU-wide register, which has been targeted by USTR as being a potential trade barrier. Conversely, the US has not adopted any regulatory provisions or precautionary measures to minimize the unique risks of nanomaterials.

4. Enhanced information sharing and protection of confidential business information (CBI):

- Although cooperation and exchange of information between the EU and the US is desirable, proposals would decrease access to information by regulators, businesses and the public, hampering efforts to transition away from toxic chemicals.

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[x] Health and Environment Alliance (HEAL), Health costs in the EU: How much is related to Endocrine Disrupting Chemicals? (June 2014), available at: http://www.env-health.org/IMG/pdf/18062014_final_health_costs_in_the_european_union_how_much_is_realted_to_edcs.pdf

[xi] European Commission, Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation (June 2014), available at: http://ec.europa.eu/smart-regulation/impact/planned_ia/docs/2014_env_009_endocrine_disruptors_en.pdf

[xii] USTR, 2014 Report on Technical Barriers to Trade, 68-70 (2014), available at: http://www.ustr.gov/sites/default/files/2014%20TBT%20Report.pdf; see also PAN, Press Release: Endocrine Disruption Criteria Update: A roadmap to nowhere (18 June 2014), available at: http://www.pan-europe.info/News/PR/140618.html

[xiii] USTR, 2014 Report on Technical Barriers to Trade, 72 (2014), available at: http://www.ustr.gov/sites/default/files/2014%20TBT%20Report.pdf

- Without TTIP, EPA already has the authority to compel industry to provide information submitted to EU regulatory authorities under existing law. The suggestion that this information should only be exchanged with the rights-holder's (industry's) approval undermines the public's right-to-know.

- In addition, the information provided to, or required by, regulators is substantially different under US and EU laws. While the US requires the complete health and safety studies for risk assessment and risk management, EU regulators require that only "robust summaries" of health and safety data be submitted. US regulators do not view these industry-generated summaries a sufficient basis for risk assessment and risk management decisions.

- Moreover, there are significant substantive differences between relevant US and EU laws on access to information, trade secrets and confidential business information. For example, unlike the US, the EU is party to the Aarhus Convention, which obliges Parties to disclose and disseminate certain environmental information. In particular, under the Convention, information on emissions into the environment, such as information on scenarios of exposure to chemicals, cannot be considered confidential.

CONCLUSIONS AND RECOMMENDATION

Rather than continuing to debate these counterproductive proposals, we call on the European Commission to insist the US commit to the EU's policy to implement by 2018 a strategy for a non-toxic environment that is conducive to public health, innovation, and the development of sustainable substitutes. This would require a deep and sorely needed structural reform of US chemicals legislation that would bring US standards closer to the comparatively stronger EU policies. Weak proposals recently considered in the US Senate and House of Representatives fall far short of what is needed to achieve this reform, protect public health, and bring the regulatory landscapes of the two partners into closer alignment, respectively. Reform of TSCA, including the ability for EPA to effectively identify, evaluate and restrict chemicals of concern, is a fundamental precondition to trans-Atlantic regulatory cooperation on chemicals. If regulatory cooperation is truly sought between the EU and US by the chemical industry, TSCA reform bills would bear at least some meaningful similarity to EU laws and policies. At present, they bear none.

Absent legislative reforms that enable the US to commit to a systematic substitution of hazardous chemicals with safer alternatives and demonstrated experience implementing that legislation, CIEL and ClientEarth maintain that the regulatory cooperation agenda of TTIP--including horizontal chapters and subsidiary annexes on chemicals, textiles, cosmetics and pesticides— poses a serious threat to public health and environmental safety and an abnegation of a fundamental government responsibility on both sides of the Atlantic, with no benefits to the public or regulators in terms of efficiency.

Annex I

List of processes where participation is granted under REACH and CLP

NOTE: EPA rulemakings under TSCA must adhere to the Administrative Procedures Act (APA), which provides for public notice and opportunity for public comment, and note the broad definition of persons in APA Section 501 (2).

Restrictions:

- Proposals for restrictions undergo public consultations for 6 months (15 consultations since 2010).
- The opinions of the two scientific committees of ECHA undergo further public consultation (9 consultations since 2011).

The US has not banned or restricted a chemical under TSCA since 1990 (Hexavant Chromium), after failing to ban asbestos in 1991.

Authorisation:

- Inclusion of a substance in the candidate list of substances of very high concern: 45 days public consultation on the proposal for inclusion [every 6 months]. The submitter of the proposal has an obligation to respond to all comments.
- Prioritisation of SVHCs for inclusion in the candidate list: 3 months public consultation on the recommendation from ECHA [once per year].
- Applications for authorization for continued use of an SVHC: 8 weeks public consultation on the existence of available alternative substances or technologies for the use applied for [on a rolling basis – 35 since August 2013].

There is no corresponding process under US law to prohibit the use of carcinogens or other substances of very high concern, unless authorized.

Evaluation:

- Inclusion of substances in the community rolling action plan (CoRAP): no public consultation is foreseen but accredited stakeholders from industry and civil society can provide comments to the process [updated every year].
- Draft decisions on substance evaluation are discussed by the Member States Committee [about 35 per year]

Under the US ”IRIS” system, the assessment of chemicals has taken over 20 year for likely or known carcinogens. Public consultation is allowed.

Classification and labeling:

- Harmonised classification and labeling: 45 days public consultation for each proposal [173 since 2009]

There is no harmonized classification procedure under US law.