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## **TTIP and the environment: the case of chemicals policy**

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Disputes over trade and environment are not seldom superficial and the ongoing debate on the Transatlantic Trade and Investment Partnership (TTIP) is not an exception. This article, however, seeks to provide an in-depth analysis in one of the areas being negotiated, namely chemicals management. It is shown that both policy and legislation in the area differ fundamentally between the EU and the USA, so neither harmonization of laws, nor harmonization of the implementation of laws is concluded to be plausible. Similarly, the prospects to harmonize the development of future chemicals legislation are concluded to be less than modest, and any institution for transatlantic regulatory collaboration in the area risks causing a regulatory chill effect at the expense of public health and the environment. The exception would be if US legislators would strengthen policy to the EU's higher level of precautionary protection, but such a policy change has for a long time proved impossible in the chemicals area.

**Keywords:** precaution; REACH; regulatory chill; trade; TSCA

### **Introduction**

Constant conflict may be good politics but in the real world, cooperation works better. (William J. Clinton)

Few issues in contemporary economic debate are as contested as trade liberalization. This has been manifested not least during the World Trade Organization (WTO) negotiation rounds. Everything from riots and perfectly legitimate civil protests, to conflicts between and within trade coalitions, characterized the recurrent WTO ministerial meetings. Sometimes the tensions were strong enough to block meetings from coming to final conclusion, as was the case in Seattle 1999 and in Cancun 2003. True conflicts, lack of trust between negotiating parties and criticism from disparate interest groups eventually moved the focus to bilateral and regional trade negotiations, which received significantly less attention. Trade issues became more technical, less politicized.

Today, the situation is changing again, with the Transatlantic Trade and Investment Partnership (TTIP) moving into the spotlight. The WTO experiences from the past seem to constitute the scene and the analytical frame for many debaters. The rhetoric is again becoming simplistic, with nearly everything from heaven to hell being portrayed as the potential outcome of TTIP negotiations. The naïve free traders focus on the potential benefits and overlook comments pointing

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at problems in the light of sustainable development, whereas just as naïve trade critics refuse to recognize even the slightest chance that benefits might exceed costs at the end of the day.

The challenges this increasingly tense situation cause for the broader debate are significant. On top of that, the chances for media and the public to take part in a comprehensive overview and balanced analysis are obstructed when official TTIP positions are held secret across the Atlantic.

This brings me to the aim of this article, to analyse in more detail the prospects and challenges in one contested area of the negotiations, namely the relationship between trade liberalization and environmental policy. Obviously, a number of issues arise here and in order to enable an in-depth analysis, I will focus this brief article on industrial chemicals policy and some of the elements that have been debated and potentially are negotiated. I write potentially, since not even those who follow these issues closely know the full details about which positions public policy-makers are discussing, a fact quite embarrassing for countries and regions calling themselves democratic.<sup>1</sup>

In particular, I will focus on the debated potential to harmonize laws for industrial chemicals fully, to harmonize implementation of these laws and to collaborate on harmonizing future legislation. I will not analyse other more or less related issues in chemicals and environmental policy, such as cosmetics or energy, nor the proposed Investor State Dispute Settlement (ISDS) mechanism, in spite of challenges in these fields as well. In the final section, however, I still hope to be able to draw some more general, at least preliminary, conclusions on TTIP and the environment. My ultimate aim is to provide food for thought, informed dialogue and cooperation.

Since a lot of material on TTIP is secret, I want to underline the methodological challenge at hand, in particular since negotiations continuously lead to new proposals and positions and thus a moving, partly hidden target.<sup>2</sup> Nevertheless, the conclusions are sufficiently valid in the focused area, and they are also likely to have a more general meaning for the trade and environment discussion in the context of TTIP.

### *A confession*

Before I move on, however, it seems well placed to make a confession, addressed to naïve debaters in all corners: I see clear benefits in trade. Anyone thinking about trade should realize that without trade, within or between countries, individual or national self-sufficiency would be necessary, which would be impossible in today's globalized world. Trade has followed mankind for ages and trade is a far more civilized way to reap benefits of resources in other territories than by conquest, an insight of value not least for the European continent. As widely known, basic economic theory on comparative advantages and specialization supports this and shows that political manoeuvres that distort trade, for example by tariffs, might have negative welfare implications.

Just as obvious though, both theory and experiences show that such political measures to protect citizens, companies or markets may well be motivated from a welfare point of view. This is true not least in cases when trading partners are faced with very different challenges, one example being when a so-called developing country needs to impose safeguards in order to help develop agriculture and alleviate poverty (Malhotra, 2003). Similarly, if environmental costs are not fully internalized, increasing trade can worsen the problems, with negative welfare effects as overall result (Ekins, Folke, & Costanza, 1994). To prevent this magnifying effect of trade, public policies are more often than not needed.

All in all it is evident that "free trade" is a too simplistic slogan. What counts in reality is what is traded (e.g. guns or solar cells), between which parties (e.g. rich or poor) and under which conditions (e.g. agricultural subsidies or environmental policy). Depending on design, deregulation for trade can either promote or prevent sustainable development. Conversely, multilateral

environmental agreements can either stimulate or impede trade, the latter motivated not least under weak environmental policies. I will now turn to these various aspects in the area of TTIP and industrials chemicals policy.

First, I will describe the case as such, the challenges and the policies and laws in the EU and the USA. Since not only the devil, but also the principles, often are in the details, this will by necessity be somewhat precise. Second, I will analyse the prospects for some of the commonly requested trade liberalization measures in the area. Finally, I will place the analysis on chemicals policy and TTIP in a broader context, closing with some proposals for the coming debate.

### **The challenges in focus: chemicals and laws in the EU and the USA**

Industrial chemicals are indispensable in daily life, medicine, industry and agriculture. At the same time, many chemicals have been shown to cause *severe* problems, such as cancer and decline of biodiversity (Bergman, Heindel, Jobling, Kidd, & Zoeller, 2013; EEA, 1998, 2007), and so far only a minority of the substances on the market has been studied thoroughly (Allanou, Hansen, & van der Bilt, 1999; Gilbert, 2011; Roe, Pease, Florini, & Silbergeld, 1997). Since substances are tested one by one, even less is known about the effects of the chemical mixtures that citizens are exposed to daily (Kortenkamp, Backhaus, & Faust, 2009). Moreover, the limited data brought to public attention by scientists, agencies and companies have more often than not been heavily disputed (Eriksson, Karlsson, & Reuter, 2010a, 2010b).

From a governance point of view, the situation is therefore quite challenging, to say the least. Interestingly, the EU and the USA have chosen to deal with this situation in very different ways. While the EU in recent years has recognized and, by developing new laws, attempted to deal with scientific uncertainty, the same cannot be said about the USA, where a nearly four decade-old regulatory framework is heavily criticized. In the following, I will describe the situation in more detail.<sup>3</sup>

#### ***EU chemicals policy***

Motivated by the need to harmonize market regulation, EU chemicals policy emerged in the 1960s and 1970s with legislation on, for example, classification and restrictions (EEC, 1967, 1976). Since then, numerous directives and regulations have been enacted and span from specific products, such as pharmaceuticals, to waste management (Jans & Vedder, 2012). Out of the 100,106 “existing” industrial substances registered in 1981, a 1993 regulation included 141 (i.e. 0.14%) in a risk assessment programme (EEC, 1993). Due to uncertainties, controversies and a strong burden of proof on regulators, the process was slow and ineffective, which led to calls for more stringent laws and implementation of the precautionary principle (Environment Council, 1999).<sup>4</sup>

After a 2001 White Paper (European Commission, 2001) and a much contested debate (Fisher, 2008), the REACH Regulation was adopted (EC, 2006), underpinned by the precautionary principle. REACH includes both existing and new substances, but covers far from all groups of chemicals. REACH firstly requires companies to register substance dossiers at the European Chemicals Agency (ECHA), with data demands depending on, for example, volume and substance properties. With quite a number of exemptions, a substance not registered, must not be put on the market. This “no data, no market” set-up reverses the burden of proof in line with the precautionary principle.

Secondly, substances can be targets for evaluation. However, ECHA checks compliance for only a few percent of the dossiers and manufacturing may start even if further testing is

needed. In parallel though, substances considered problematic may be more thoroughly evaluated and, potentially, targets for one of the two following risk management strategies.

The first, *authorization*, focuses on “substances of very high concern” (SVHCs), for instance those being toxic, or “very persistent and very bioaccumulative”.<sup>5</sup> ECHA can place a SVHC on a “Candidate List”, which leads to certain information requirements along supply chains and to citizens. If ECHA also prioritizes and recommends a SVHC, the Commission may place it on a list for authorization, often after a lengthy committee procedure involving, for example, EU member states. Once on the list, the SVHC must not be used after a sunset date, unless authorization is granted after further process, involving new committees and analysis of, for example, “adequate control”, potential substitutes and socioeconomic aspects. During listing, the burden of proof rests with regulators. At present, the Candidate List contains 155 substances, of which 31 are listed for authorization.<sup>6</sup> These small numbers can be compared with assumptions in the White Paper to authorize 1400 substances (European Commission, 2001).

Alternatively, *restrictions* may be adopted in individual cases of “unacceptable risk”. Here as well, the procedure takes a long time and is complex, including various committees that consider, for example, risks and socioeconomic parameters. The burden of proof again rests on the public side, so restrictions are in principle just as difficult to impose as before REACH. Usually restriction processes are heavily politicized and time-consuming, and slow down the legal implementation (Eriksson et al., 2010a).

### ***US chemicals policy***

As in the EU, US chemicals policy goes back quite some time and several acts regulate various issues on, for example, consumer product safety and food and drugs. The central piece of law is the Toxic Substances Control Act (TSCA, 1976), which focuses on industrial chemicals. TSCA has basically remained intact for nearly 40 years, in spite of several amendment proposals, the most recent being the Chemicals Safety Improvement Act (S, 2013).

TSCA differentiates between existing and new chemicals and assigns the US Environmental Protection Agency (EPA) to implement the law. Despite being introduced 30 years earlier, TSCA was just as REACH a reaction to governance problems due to uncertainties (CEQ, 1971), and Congress wanted to shift the burden of proof and make industry responsible for data generation (Applegate, 2008).

Under TSCA, firstly, the EPA may require substance testing if needed to fill data gaps. To complete such a process takes years, however, and only a couple of hundred substances have been targeted (OPPT, 2008). A key reason is that the EPA needs to demonstrate that a substance “may present an unreasonable risk” before data can be demanded, but that usually presupposes the data that are missing, implying a legal Catch 22. Secondly, TSCA requires a “premanufacture notification” (PMN) to be submitted for new substances, or significant new uses of an existing substance. Testing is not required though, even if key data are missing. Under some conditions, pending more data, the EPA can restrict a substance, but that has hardly ever happened (OPPT, 2008). Thirdly, regarding existing substances, the EPA may issue restrictions (on e.g. manufacturing, labelling and use) if there is reasonable support that a substance “will present an unreasonable risk” (i.e. the required level of evidence is higher here). TSCA does not define “unreasonable risk”, but besides analysing the risks at hand, also the effects on economy, business and innovation must be considered.

In summary, TSCA has not at all delivered what was anticipated (Applegate, 2008; Ashford, 2007; Denison, 2009) and only a handful of substances have been restricted (OPPT, 2008). In addition, courts have the power to set aside EPA decisions if substantial evidence cannot be shown, for example that an agency requirement is the “least burdensome” (a ruling on asbestos

showed legal gaps here, see GAO, 2007). For these and other reasons (e.g. budgetary constraints), the EPA often needs to work with voluntary agreements (e.g. the High Production Volume Challenge Programme), guidance and information sharing. This has improved data generation and risk management, but in total, severe shortcomings exist. Similar to REACH, TSCA also prevents disclosure of much information that is considered to be trade secrets.

### **Analysing TTIP negotiation points on chemicals**

I trust that readers of this journal have a fairly good idea of the basic background to the TTIP negotiations, which President Obama and European Commission President Barroso launched in June 2013. In order to simplify the following exercise, I will not try to detail or discuss which proposals and negotiating positions, if any, related to industrial chemicals that are more likely than others to survive in the end (and today the answers depends on who you listen to). Instead, I will use a more straightforward approach and group and focus on some more or less detailed proposals that indeed are or have been floating around in the debate,<sup>7</sup> disregarding negotiators' present view on whether these ideas are dead or alive in the talks behind closed doors. More precisely, I will focus on: (1) harmonizing laws (e.g. basic principles and substantive provisions); (2) harmonizing the implementation of laws (e.g. testing requirements, prioritization); and (3) regulatory collaboration on future legislation (e.g. the proposed Regulatory Collaboration Committee). I realize that this cake can be cut in different pieces, but that is not of primary importance for the analysis.

### ***Harmonizing laws***

From the background provided above it is clear that REACH and TSCA are two very different pieces of law. Even if basic objectives to some extent are similar – generating data and managing risks – the basic building blocks differ fundamentally. REACH places the burden of proof for registrations and initial data delivery on companies, and includes a system with a Candidate List and potential authorization requirements for SVHCs, including substances that are not necessarily considered toxic. To some extent, REACH is thus implementing a hazard-based approach in line with the precautionary principle. TSCA offers nothing similar and has a strong risk-based character, where the burden of proof rests strongly with the EPA to show not only inherent hazardous properties of a substance, but also unacceptable exposure conditions (in a risk assessment) before various measures can be taken. Even if there are shortcomings in REACH and in the implementation of REACH,<sup>8</sup> TSCA is still not even close to offering the same level of protection. A major harmonization of these laws, if at all desirable, would for these reasons not be possible without rewriting them fundamentally. The chances of that happening in the near future are negligible, to judge from the recent REACH review (European Commission, 2013) and the fate of the proposed TSCA amendments so far.

This conclusion is pretty obvious and even though I still hear some politicians advocating full legal harmonization for industrial chemicals, national agencies (Swedish National Board of Trade, 2014), the European Commission (2014a) and the chemicals industry (CEFIC, 2014) nowadays take a quite similar position on this point.

### ***Harmonizing implementation***

Given the shared view that basic legal harmonization is not feasible, it is all the more surprising to see proposals for harmonization of various aspects of implementation of REACH and TSCA, for instance regarding science, risk assessment, classification, data requirements and prioritization

among substances.<sup>9</sup> Given the huge knowledge gaps, international data sharing is of course valuable, but it hardly requires a trade treaty. New information on substance properties is already shared by scientific publications and international collaboration,<sup>10</sup> which could and preferably should be enhanced. However, harmonizing the work in scientific or risk assessment committees would be a matter of much more than practical consultation and coordination. The activities undertaken in such committees are commonly far from objective and uncontroversial exercises. On the contrary, they are based on publicly decided normative starting points, as well as on not so evident personal views among participating experts, and are therefore very time consuming (Eriksson et al., 2010b; Sass & Rosenberg, 2011). Setting up joint scientific committees across the Atlantic, charging them to publish conclusions on chemicals risk, would therefore most likely further delay urgent data delivery and risk management. In addition, seeking an EU–US deal on substance classification would risk impeding implementation of the already existing global UN system for harmonization in this field.<sup>11</sup> Moreover, any EU–US harmonization of prioritization among substances would probably be even more problematic, since the legal basis for doing so, as shown, is far from similar.<sup>12</sup> For instance, most hazard-based provisions in REACH<sup>13</sup> have no resemblance in TSCA, so harmonizing implementation in this area would necessitate fundamental principal amendments of either law. Since it has clearly been stated that the level of protection in REACH must not decrease as a result of TTIP,<sup>14</sup> and since all attempts to amend TSCA principally have failed, the prospects of agreement on these issues within the negotiation timeframe of a year or two seem, at best, very limited. Finally, regarding testing methods as such, international harmonization and collaboration has already been taking place for more than three decades within the frames of OECD collaboration. It is very unclear what a TTIP deal could add here.

To summarize, it is far from certain that it would be easier to harmonize the implementation of two fundamentally different laws, with partially incompatible underlying values and principles, than it would be to harmonize the laws as such.

### ***Regulatory collaboration on future legislation***

When it comes to collaboration on future regulation, the basic critical point is more or less the same as above. When the normative set-up of two legal systems differs, based on diverging political views on central values (such as the desired level of protection, and the view on risk, precaution and responsibility), the prospects for harmonization of future regulation are very modest. Setting up one kind or another of a Regulatory Cooperation Council – which has been proposed to, for example, oversee regulatory processes,<sup>15</sup> carry out consultations and impact assessments (e.g. cost–benefit or trade–impact analysis) – therefore seems to be a nearly impossible task, at least if efficiency and effectiveness in decision making are desired. Most likely, such a council would slow down processes and seriously impede any new regulation. Already mentioning issues like precaution, substitution, decisions based on inherent properties, regulating effects of mixtures, criteria for endocrine-disrupting chemicals, definitions of nanoparticles and regulation of products with hazardous substances, commonly triggers drawn-out debates between policy-makers *within* the EU and the USA.<sup>16</sup> Without reconciling the basic views on issues like these, and the underlying rationale for dealing with them in one way or another, agreeing on the practical set-up of new laws, or on amending existing laws, would not be helpful.

Any new institutional body here, to which a trade deal would give an indispensable and unavoidable role, would result in a regulatory chill effect, most likely being very costly for public health and the environment, in the worst case also without much insight from elected law-making politicians in, for example the European Parliament.<sup>17</sup>

## Discussion

I started out by saying that enhanced trade is desirable if it manages, for example, environmental impact. Under the present circumstances, trade liberalization under a TTIP deal in terms of reduced tariffs in the discussed chemicals area would probably as such not have any significant negative or positive implications on health or the environment. As I have shown though, harmonizing EU and US present and future laws on industrial chemicals, and the implementation of them, would most likely be very problematic. First, it would necessitate legal amendments that, as far as I can see, have not been discussed in concrete terms in the negotiations so far. Second, it would require that either the EU or the USA change their basic view on risk governance. If the EU would accept a more risk-based approach, the protection of health and the environment, at least in the EU, would be weakened. On the contrary, chemicals risk management would improve if the USA would accept a more hazard-based approach, but assuming that Congress in the near future would support such a change of basic policy is nothing more than wishful thinking.<sup>18</sup> Much speaks for a similar conclusion being valid also in related areas of environmental regulation, where there is a divided view across the Atlantic on risk and precaution at present.

It must be said though, that I do not consider this to be based on a fact that US policy per se would be anti-precaution. On the contrary, studies show (Wiener, Rogers, Hammit, & Sand, 2010) that there are areas where the USA has taken more precautionary positions than the EU in the past (ozone layer protection), and at present in some cases (particulate matter), but also that the EU today is more precautionary in areas of, for example, chemicals and climate policies. Moreover, it is still contested whether a shift is taking place, so that the EU is steadily becoming more precautionary (Vogel, 2012), or if there is a regulatory pendulum swinging back and forth across the Atlantic, changing policies on both sides over time (Löfstedt, 2004). If the latter holds true, future convergence of chemicals legislation would not be impossible, but it is highly unlikely that the practical road to such changes would be a deal on TTIP, even if negotiations could give an impetus to that.

In reality though, there is rather a need for an open transatlantic discussion on how policy and legislation can be improved to strengthen the protection of public health and the environment, on both sides of the Atlantic.<sup>19</sup> Instead of simplistic jargon about trade, such a dialogue would benefit from more of in-depth analysis, nuanced argumentation and transparent cooperation.

## Notes on contributor

Dr Mikael Karlsson is an agronomist and holds a PhD in Environmental and Energy Systems. His research focuses on environmental policy, risk governance, and science and technology studies, with publications on e.g. chemicals law, marine governance, climate policy and responsible procurement. Dr Karlsson is President of the European Environmental Bureau, Europe's largest environmental organisation, and for the last twelve years he worked as President of the Swedish Society for Nature Conservation. He is an Independent Specialist in the Swedish Government's Cross-Party Committee on Environmental Objectives and has served as expert in numerous agencies and public committees on environmental policy in Sweden and the EU, including in High-Level Groups at the European Commission. Dr Karlsson is 45 years and lives in Stockholm with his family.

## Notes

1. At the time of writing (9 October 2014), the European Commission praised itself for declassifying a secret document on a negotiating mandate (<http://trade.ec.europa.eu/doclib/press/index.cfm?id=1162>), even though it only revealed some (general) positions, and came out after far more detailed leaked documents were published (see e.g. [http://ciel.org/Publications/TTIP\\_Chem\\_16Sep2014.pdf](http://ciel.org/Publications/TTIP_Chem_16Sep2014.pdf) with associated commentary at [http://ciel.org/Publications/TTIP\\_Leaked\\_29Sep2014.pdf](http://ciel.org/Publications/TTIP_Leaked_29Sep2014.pdf)).

2. The article was for example written before the European Commission's "TTIP chemicals – revised versions on papers on outline of provisions and modalities for cooperation" was leaked on 1 October 2014 (see note 1), but the substance in that paper does not prompt significant changes of the analysis or conclusions in this article.
3. See Karlsson (2010) for a more comprehensive description and analysis of the EU Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and the US Toxic Substances Control Act (TSCA), including on risk management aspects not dealt with here (e.g. information sharing requirements).
4. Precaution has a long history in, for example, Sweden and Germany, became part of the EC Treaty (1992) and has been developed by the European Commission (2000); see Karlsson (2006) for an analysis.
5. This "vPvB-category" is one example of a hazard-based element in REACH.
6. See [http://echa.europa.eu/sv/view-article/-/journal\\_content/title/candidate-list-updated-with-four-new-svhcs](http://echa.europa.eu/sv/view-article/-/journal_content/title/candidate-list-updated-with-four-new-svhcs); <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list>.
7. See, for example, the leaked European Commission document referred to in note 1; CEFIC and ACC (2012); CEFIC (2014a); European Commission (2014a); ACC (2013); European Commission (2014b). See also CIEL and ClientEarth (2014) on some of the associated problems.
8. See, for example, European Commission (2013) with links; and ClientEarth and EEB (2012), with the response from the European Chemicals Agency (ECHA): [http://echa.europa.eu/documents/10162/13556/response\\_to\\_eeb\\_and\\_clientearth\\_20121026\\_en.pdf](http://echa.europa.eu/documents/10162/13556/response_to_eeb_and_clientearth_20121026_en.pdf).
9. See, for example, references in note 1 and CEFIC (2014b).
10. ECHA and the EPA already collaborate, for example.
11. See further on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) on [http://www.unece.org/trans/danger/publi/ghs/ghs\\_welcome\\_e.html](http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html).
12. See also CIEL and ClientEarth (2014) on the limited overlap between EU and US priority lists.
13. These focus, for example, on inherent properties of substances, including toxicity, persistency and capacity to bioaccumulate.
14. If this holds true, parts of the often claimed benefits of TTIP (amounting for the EU to the modest growth increase of some 0.01% per year (see Erixon and Bauer, 2010) will not be realized since that presumes a harmonization that then would not take place.
15. Even on the state level in the USA and for member states in the EU.
16. The USTR (2014) report on "technical barriers to trade" reveals clearly some of the differences in view *between* the USA and the EU, for example on Endocrine Disrupting Chemicals (EDCs).
17. Even though not discussed here, an inclusion of the proposed ISDS mechanism would most likely also cause similar kinds of chill effects (see e.g. Stiglitz, 2013; CIEL and ClientEarth, 2014; and Gerstetter et al., 2013).
18. There might of course be intermediate positions besides those I have discussed where partial harmonization could be possible at present, and the risk–hazard divide is not always so deep as claimed (see e.g. Karlsson, 2011), but that would hardly relate to any principles or substantial provisions of importance.
19. Such legal development can support competitiveness and boost innovation (Karlsson, 2006; see also CIEL (2013). For ideas on various paths to global chemical safety, see [http://www.naturskyddsforeningen.se/sites/default/files/dokument-media/rapport\\_paths\\_to\\_global\\_chemical\\_safety.pdf](http://www.naturskyddsforeningen.se/sites/default/files/dokument-media/rapport_paths_to_global_chemical_safety.pdf).

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