

13. GREATER TTIP AMBITION IN CHEMICALS: WHY AND HOW

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Politics is the art of the possible.
Otto Von Bismarck (1867).

1. Introduction and purpose

This chapter discusses the chemicals chapter of the Transatlantic Trade and Investment Partnership (TTIP), in particular the regulatory part. The flaw we see in US-EU chemical regulatory cooperation is that the focus has been far too much on the differences in procedures between the two regulatory systems rather than on what ultimately matters: the actual *level* of SHEC (safety, health, environment and consumer) protection provided for substances that are regulated by both the EU and the US. This flaw is still valid today in TTIP. The only difference is that the TTIP initiative is being sold as far more ambitious in terms of regulatory cooperation for the North Atlantic than ever before, and that it might also influence regulatory ambitions of other WTO partners. But this prospect seems not to apply to chemicals, which is precisely one motivation of the chapter. To date, the TTIP talks over chemicals have not been ambitious enough in our view and there is no chance whatsoever that a TTIP chemical regime will emerge as a shining example for the rest of the world. Within the confines of this chapter, we shall attempt to demonstrate that it is far more productive to focus on the identification of equivalent levels of protection against risky chemical substances than to harp on the ‘systemic’ divergences.

So far, the political and societal debates on the chemical aspects of TTIP have been neither productive nor constructive. They are stuck in stereotypes that are believed simply because certain forces keep on repeating them endlessly, rather than systematically scrutinising the various arguments. Outside industry (but in the present climate,

industry suffers from a credibility problem, rightly or wrongly), few, if any, experts or independent analysts take the trouble to publish careful assessments and steer the public debate into fact-finding and constructive analyses. Assertions about a lowering of levels of protection are repeated, although such lowering was neither explicit nor implicit in the mandate; indeed, the opposite is found in writings and in numerous statements of the EU and by the negotiators on both sides. Discussions tend to be elusive or highly principled, complemented by plenty of accusations, misunderstandings, caricatures, recriminations or indeed outright suspicion. In such a political climate for the case of chemicals, the original ideas behind TTIP tend to be forgotten or dismissed without any search for the facts or for solid ideas. Such a style of 'debating' and the creation of a climate of profound suspicion, despite the distinct separation between the untouchable level(s) of protection and having a focus on the instruments (as indeed is done for other TTIP sectoral annexes), is not in keeping with the aim and spirit of TTIP. It cannot be in the EU and/or US public interest either.

The aim of our chapter is to introduce at least the beginnings of a fruitful factual analysis of what can and cannot be done in chemicals in TTIP and why. Our chapter will not deeply discuss the differences between the two systems, as this has been done before: this divergence is, for now, far too great. Nevertheless, the knowledge and understanding of how the US regulates chemicals are poor in Europe and therefore we do offer a concise 'primer' on it (see Box 13.1 in section 4). However, agreeing that 'the systems' are different is not the end of the story but precisely the beginning! Protecting citizens and workers against risky chemicals is less a matter of systems and much more, if not decisively, a matter of checking the protection in terms of results for each and every substance. When focusing on the level of protection against risky chemicals – and *not* on 'the systems' or their equivalence – we shall focus on two possibilities: one is TTIP action when, for individual substances, the level of protection is found to be equivalent in the US and EU, and the other is an opt-in choice for companies to the more stringent regime for substances that are regulated on both sides, automatically allowing access to the market with the less-stringent regime but at the price of following the more-restrictive standard in both markets. The EU and the US can act together in TTIP and in its living agreement in all cases where the level of protection is adequate, despite the systemic differences of how this came about. However, where equivalence of protection levels is found, it is far from easy to

appreciate what *can* be done and requires innovative policy thinking. This is what our chapter attempts to do, in the spirit of TTIP as first formulated in the US-EU High Level Group (2013) and later in the TTIP mandates.

The structure of the chapter is as follows. We begin by querying whether the often-mentioned ‘systemic’ divergences in chemical regulation of the US and the EU are a justifiable reason to remain unambitious in TTIP. The present authors do not think so. Instead, the ultimate goals of chemical regulation should be the main focus of TTIP: where exactly are the levels of protection similar and where not, and when similar, can the trading costs, in particular duplications of many costly obligations, be addressed? In section 3 we observe that the TTIP chemicals discussions are modest, in sharp contrast with suggestions, at high transatlantic level, nearly two decades ago. Have all such efforts come to nothing at all? This is elaborated in section 4, recalling US-EU chemical regulatory cooperation since the mid-1990s. In the late 1990s, proposals were far more ambitious than even TTIP is today! It is no exaggeration to characterise the intervening period as an era of missed opportunities, whether selective harmonisation, carefully crafted mutual recognition or targeted equivalence agreements. Section 5 explains in some detail how modestly TTIP is now pursued in chemicals. Unfortunately, the information on the US position is scant, and no transparency has been provided so far. Therefore, we mainly rely on the EU positioning. The EU proposals, as published in November 2014, are summarised in Box 13.3. However, we have also inserted a Box 13.2 on the OECD’s accomplishments in chemicals regulatory cooperation; this begs the question of how much more ambitious TTIP in chemicals really is. Some highly tentative discussion of the unspoken background to the proposals in Box 13.3 is provided as well.

This discussion is followed by two sections: one (section 6) about perceptions and criticism when contrasting the EU’s Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and the US Toxic Substances Control Act (TSCA,) and section 7 about ‘frozen’ policy attitudes in Brussels and Washington, under the heading ‘carved in stone’. A brief and inevitably incomplete discussion of the links with a global regime, so important now that the share of non-TTIP chemical production in the world is increasing steadily, is provided in section 8. It deals with potential positive spill-overs and US objections against REACH as the basis for a world regime. Our approach to eventually facilitate mutual market access between the US

and the EU, highly tentative to be sure, is spelled out in section 9. As noted, it focuses on SHEC (safety, health, environment and consumer) objectives and functional equivalence of protection against risky substances, in areas where the level of legal regulation is similar or allowing companies to opt into abiding by the more stringent system everywhere. The latter can improve market access immediately, as an early harvest in TTIP, and is spelled out in section 10. The final section 11 concludes.

2. Divergences in regulatory systems are not the right focus in TTIP

A quarter century ago, during the heyday of rational actor models derived from neo-classical economics, UC Berkeley political scientist and business professor David Vogel made a powerful prediction that trade negotiations would result in ‘harmonising up’. By that term, he meant adopting the more stringent or precautionary environmental or consumer standards in order to obtain the efficiency gains that come from eliminating inconsistencies that impede trade for mutual gain.

Trade liberalization is most likely to *strengthen* consumer and environmental protection when a group of nations has agreed to reduce the role of regulations as trade barriers and the most powerful among them has influential domestic constituencies that support stronger regulatory standards.¹

As book goes to press, it seems highly unlikely that Vogel’s prediction for ‘harmonising up’ will come to pass in the TTIP negotiations for chemicals. NGOs and mass publics on both sides of the Atlantic are concerned that TTIP will become an excuse for ‘rolling back’ regulatory protections.² Both negotiating parties seem wedded to

¹ See Vogel (2012, p. 8). In fairness, Vogel did include a number of caveats, including that there must be powerful support for the tougher standards in the domestic politics of the “most powerful” nation in the trade talks. Unlike NAFTA, which was the model uppermost in Vogel’s mind, the EU-US negotiations are taking place between two relative equals in economic power.

² See Matthew Dalton, “TTIP Could Weaken Chemical Rules, Environmental Groups Say”, Wall Street Journal Real Time Brussels Blog, 7 October 2014 (<http://blogs.wsj.com/brussels/2014/10/07/ttip-could-weaken-chemical-rules-environmental-groups-say/>). On both sides of the Atlantic, NGOs, often jointly, keep repeating these types of messages of doubt, if not suspicion. On 10 July 2014, no less than 111 (!) NGOs – 30 of which were EU organisations and 78 US – wrote a letter to top TTIP negotiators Michael Froman and Karel De

sticking with their own systems for regulating the health and safety issues relating to chemical usage.

The goal of this chapter is to explain why the current negotiations seem unlikely to result in mutually-beneficial 'harmonising up', as suggested by Vogel's logic, and to recommend ways in which we can eventually achieve more North Atlantic regulatory cooperation in chemicals, in particular, by reducing the costs and instances of pointless duplication in the future. We consider several possible explanations for why the current negotiations did not set more ambitious goals for the chemicals sector, but in the final analysis, we conclude that the two sides cannot yet agree on what constitutes 'up': European governments, industry trade associations and the general public generally perceive their recently-enacted Regulation on registration, evaluation, authorisation and restriction of chemicals (REACH) as providing better protection than does the US system,³ as also do some US academics and NGOs. US companies and negotiators, however, are loathe to adopt the REACH system, which they perceive as being overly 'precautionary' and unduly burdensome.⁴ This problem of

Gucht, with an annex spelling out seven types of concerns. A return letter from Commissioner De Gucht dated 2 October 2014, firmly dismissed all seven concerns in clear terms. For reasons that are hard to understand, however, this clear rebuttal seems almost irrelevant for (at least) some NGOs, because statements of doubt and fear are still reiterated. Just one more recent example is BUND (2015). It would take a separate paper to try to understand this NGO's tendency to make long-rejected allegations on TTIP all the time. One wonders, for instance, whether European NGOs and some sceptical MEPs do not believe that the European Commission is capable of sticking to the levels of protection in the TTIP negotiations and would not be lured into 'issue linkages' or trade-offs on this question.

³ Of course, it will be remembered that the enactment of the REACH Regulation late in 2006 took place amidst enormous controversy. Now that REACH is EU law, there seems little point in continuing the debate, but this does not mean that REACH is well accepted. What is accepted are the objectives of REACH, much less (or rejected) the high costs.

⁴ As this book goes to press, long-pending legislation in the US Congress to adopt a somewhat more 'REACH-like' system of national chemical regulation has cleared some important hurdles but still faces others (Kollipara, 2015). TSCA Reform has been passed by the House, and it now seems that the US Senate may pass it in early August, and a merged version of the two (House and Senate bills) might well go to the US President for signature in September 2015. Even if TSCA reform is eventually enacted, it will take many years to be

divergent perceptions of the effectiveness of the other sides' regulatory system is not limited to chemicals. These perceptions (or misperceptions) are inverted for other sectors: some Americans perceive European regulation of automobiles as 'weaker' than theirs,⁵ and they, like Europeans regarding chemicals, are so far unwilling to 'roll back' existing protections in order to strike a trade deal.

These perceptions are probably at least in part caricatures. The most amazing are the perceptions of some (mostly European) NGOs and indeed citizens (e.g. in social media and in advocacy activities) about how Americans seem to live with woefully inadequate protection against risky chemicals. The caricature amounts to the notion that Americans are swimming in a toxic soup of dangerous chemicals every day! Few if any in Europe appear to have second thoughts about such caricatures, as if American citizens and workers would easily accept such a predicament, as if liability would not undo this at least in part, as if many other laws than TSCA do not exist (which actually have the effect of regulating many substances). If it were so bad, have Americans (and especially workers) contracted many diseases associated with such unregulated risky chemicals to an extent not found⁶ in Europe? The surprising fact remains that there is very little objective data that would allow a neutral observer to assess whether it is so bad in the US, or, more generally, which side is 'right'. In addition, the actual situation

implemented through regulations and enforcement and to gain credibility in Europe.

⁵ See Brad Berman, "Lusting for Europe's Illegal 60-MPG Cars", 8 December 2008 (www.hybridcars.com/lusting-europe-illegal-high-mpg-cars-25323/).

⁶ There are some instances where a substance, prohibited in the EU, may cause adverse health effects in the US, e.g. electronic devices with nickel in their cases, but is this product-specific or a general pattern? And are people actually being exposed to the nickel? Europe often regulates based on 'hazard', the presence of a potentially toxic substance, whereas the US tends to consider 'risk', which also weighs in the balance exposure and the seriousness of the harm. The seriousness of the adverse health effect might also be weighed in considering whether a ban or some other form of regulation such as a notice to susceptible populations makes sense. In the case of nickel in electronic devices, the main adverse health effect seems to be a skin rash in a small proportion of the population who are allergic to nickel. One proposed solution is to cover the nickel with a case or a lacquer to avoid skin contact (see Rita Arrup, "Electronic Devices and Nickel Allergic Reactions", Nickel Allergy Information News and Solutions, 14 July 2014 (www.nickelallergyinformation.com/2014/07/electronic_devices_and_nickel.htm)).

may be a mixed bag, in which one side regulates more stringently in some areas, and the other more stringently in others. The fact is we just don't know, although this is rarely acknowledged. Most of the literature comparing the two regimes⁷ is anecdotal and evidently not sufficient to persuade governments and their publics that the differences in actual outcomes are not as great as they are often perceived to be. That in itself is a puzzle: those who think the world is efficient would predict that both sides would invest in developing better information about how the two systems of chemicals regulation actually function so that they could make rational decisions for their mutual benefit.

That the two largest trading blocs are making important decisions about one of their largest market segments without good data about how chemicals regulation *actually* works (in terms of what is regulated and how well for SHEC protection) on the two sides of the Atlantic suggests there may well be something to a tradition older than rational actor models such as Vogel's. This alternative vision of how human beings behave emphasises the role of error and misperception, in addition to rational calculation in human affairs, and it is now experiencing a rebirth under the rubric 'behavioral law and economics'.⁸ Its essence is aptly captured in former Israeli foreign minister Abba Eban's line: "History teaches us that men and nations behave wisely once they have exhausted all other alternatives."⁹

The assumption that people are often guided by errors and misperceptions¹⁰ leads us to conclude that the negotiators on both sides of the Atlantic may not be unwise in setting modest goals after all. Greater harmonisation of chemical regulatory systems across the Atlantic may be premature. We may have to go through a period of mutual confidence-building to overcome the stereotypes and misperceptions that currently limit progress; in Abba Eban's words, we

⁷ The best work comparing risk regulation in the US and the EU concludes there is actually very little difference, but one sector or another may be more 'precautionary' on one side or the other (see Renn & Elliott, 2011). Most of the literature comparing TSCA and REACH focuses on the procedural and systemic aspects, often with a view to reforming TSCA. Examples include GAO (2007) and Applegate (2008).

⁸ See Thaler & Sunstein (2008).

⁹ Speech delivered in London, 16 December 1970, as quoted in *The Times* [London], 17 December 1970 and in *Great Jewish Quotations* (1996) by Alfred J. Kolatch, p. 115 (http://en.wikiquote.org/wiki/Abba_Eban).

¹⁰ See generally Kahneman (2011).

have to “exhaust all the other alternatives” before we can move to a more rational, more efficient system that would benefit both sides by eliminating needless duplication and inconsistency. The negotiators appear to be setting only modest goals to promote greater data-sharing and collaboration at the technical level. This might eventually lead both sides to greater convergence in regulatory outcomes and to increasing the perception that the actual substantive *results* of the two systems of chemical regulation in many areas are not that different, despite major differences in legal structure and procedure.

Our assessment of the current situation leads us to make two practical recommendations, which will be elaborated later in this chapter.

1) *Optional asymmetric harmonisation.* We recommend that the TTIP should include an optional process for ‘harmonising up’ by gradually voluntarily opting into what are perceived to be more stringent regulations on one side or the other. This would be achieved by maintaining an official list of regulations that are deemed to be more stringent by both sides and allowing companies to opt in to be governed by the concededly more stringent rules. This option would promote efficiency by eliminating duplication where the benefits of eliminating duplicative regulation are greater than the costs of over-compliance. Opting in to more stringent regulation where the costs of doing so are low also may begin a bottom-up process of creating de facto internationally harmonised regulations worldwide.

2) *Ongoing expert assessment of comparative effectiveness of regulation.* We also recommend that the TTIP should include a new institution for developing mutually credible assessments and data about the actual performance of chemicals regulation on both sides of the Atlantic. Future negotiators should not be working from the stereotypes and caricatures that currently define mutual misperceptions of the other’s system of chemicals regulation. Joint panels of experts should be convened to assess and report on where actual regulatory outcomes differ and where they are either ‘essentially equivalent’ or at least good enough to protect the public as intended.

An interesting model for such an institution was recently provided by the automobile industry. The European Automobile Manufacturers’ Association, the American Automotive Policy Council and the Alliance of Automobile Manufacturers together commissioned a recent study by two leading engineering think tanks, one American – the University of Michigan Transportation Research Institute – and one European – SAFER, a transportation research centre at Chalmers

University in Gothenburg, Sweden – to evaluate whether motor vehicles manufactured in compliance with EU and US regulatory requirements provide essentially equivalent real-world safety performance.¹¹ Although one might debate whether ‘essential (or functional) equivalence’, as opposed to ‘adequate to protect the public’,¹² is the right standard for evaluation, the model of neutral evaluation by experts on both sides of the Atlantic is a promising one. We recommend that something like this should be embodied in a permanent institution under TTIP, which would be mandated to carry out comparative studies of the effectiveness of regulation in the two trading partners and make consensus recommendations for areas where greater harmonisation would not reduce the practical level of protection on either side.¹³

3. Why did so much effort and prospective gains produce so little?

Why did so much effort produce so little convergence of regulatory systems is the over-riding question about the TTIP negotiations for the chemicals sector. In fact, a lot of effort in chemicals preceded the TTIP negotiations under the Transatlantic Market Place since 1996 and the

¹¹ See European Automobile Manufacturers’ Association Press Release, “TTIP: Study examines EU & US vehicle safety equivalence”, 21 May 2014 (www.acea.be/press-releases/article/ttip-study-examines-eu-us-vehicle-safety-equivalence). The results of this highly technical study were not yet available when the present book went to press. However, the European Commission published two practical examples of testing for equivalence, one on seat belt anchorages and one on lighting and vision standards, both of which were found functionally equivalent, despite diverging technical requirements. See http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153023.pdf and http://trade.ec.europa.eu/doclib/docs/2015/february/tradoc_153168.pdf

¹² See US Administrative Conference Recommendation 2011-6 on International Regulatory Cooperation, Paragraph 4, adopted 8 December 2011: “To deploy limited resources more effectively, agencies should, where appropriate and practicable, identify foreign authorities that maintain high quality and effective standards and practices and identify areas in which the tests, inspections, or certifications by agencies and such foreign agencies overlap.” (www.acus.gov/recommendation/international-regulatory-cooperation)

¹³ For an analysis of the political economy of recommendations by expert consensus bodies, and why they are often adopted by politicians without controversy, see Elliott (2008).

proposals of the Transatlantic Business Dialogue (TABD). As we shall remind the reader, the common chemical TABD proposals of one and a half decades ago were much bolder than what is on the table in TTIP. In chemicals, TTIP as it stands today, is anything but bold. Although the terms of a final agreement are still to be agreed, the negotiators (particularly those for the EU) have taken pains in public statements to reassure an anxious public and NGO community that “joint chemicals regulation is absolutely off the table”.¹⁴ As reported in ENDS Europe DAILY, “both [US chief negotiator Dan] Mullaney and the EU’s [chief negotiator Ignacio] Garcia Bercero emphasised that they are not considering ‘harmonising or mutually recognising’ the two regulatory systems.”¹⁵ Of course, some two decades ago, REACH did not exist. One can argue with some justification that the emergence of REACH itself has killed the ambitious proposals emerging from the TABD. However (as far as we know), no alternative approaches have been suggested by the negotiators to reduce significantly technical barriers to trade (TBTs) in chemicals trade, without reducing SHEC -protection on either side. Looking at the EU negotiation position on chemicals,¹⁶ the proposals are modest and will hardly address the high costs of TBTs in the sector.

And it is lowering TBTs that is the prime economic justification of TTIP. The present chapter is not the right place to elaborate on TBTs in chemicals trade. The most respectable study on the overall costs of TBTs and their partial removal under TTIP is Francois et al. (2013) for the Commission’s Impact Assessment. A non-technical assessment of the study and alternatives can be found in Pelkmans et al. (2014) for the European Parliament. The simulations by Francois et al. are the only ones with specific sectoral TBT estimates: for chemicals, TBT costs of EU exports to the US amount to 19.1%; for US exports to the EU, some 13.6%. These compare with chemical tariffs in the 3%-6% range, with quite a few actually being zero. This is not to suggest that these TBT estimates are rock-solid – it is exceedingly difficult to come to such estimates (which is why sectoral TBT estimates are so very rare). Moreover, in discussions with the chemicals industry, it was indicated that TBTs due to regulatory (systems) divergence are costly, no doubt,

¹⁴ “Shared Chemicals Assessment on TTIP Table”, ENDS Europe DAILY, 3 October 2014.

¹⁵ Ibid.

¹⁶ See the EU’s position on chemicals on the European Commission’s website (http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152468.pdf).

and should be reduced significantly, but these fairly high costs are not seen as a true trade barrier by the larger chemicals firms, only by the many SMEs. Still, going by the best study available (Francois et al., 2013), a halving of the TBT costs in chemicals would give a boost in mutual exports of respectively €29.9 billion (36%) for the EU and €27.3 billion (34%) for the US, which are impressive statistics by any account. It ought to be noted that these effects incorporate general equilibrium effects (e.g. also of other TTIP sectors and their relations with the chemical industry) and, moreover, are calculated on the assumption of positive spill-overs to third countries.¹⁷ However, if SMEs would find it feasible, once TTIP would have reduced TBTs significantly, to enter transatlantic trade, the economic effects would become larger still. This SME effect cannot be modelled in CGE approaches. Thus, the case for tackling TBTs in chemicals in TTIP is powerful.

This is not to say, however, that a TTIP agreement on chemicals, without lowering TBTs significantly at first, would be unimportant. An agreement, if one is eventually reached, will undoubtedly result in progress towards reducing certain trade barriers, including the elimination of (relatively low) tariffs on chemicals, as well as increased collaboration at the scientific and technical level and probably also to greater standardisation of testing methods, labelling and sharing of datasets. According to reports in the trade press, “EU and US negotiators are examining how regulators can share the work of assessing priority chemicals as part of the TTIP trade deal”¹⁸ These could lead to substantial accomplishments. Moreover, eliminating tariffs alone is estimated to save €1.5 billion annually,¹⁹ and this tariff-cutting would also avoid distorting trade by deterring transactions that

¹⁷ A spill-over of 20% has been assumed. This also has a positive effect on EU and US exports of chemicals to the rest of the world, up by some 9%. It is also good to re-emphasise that TBTs have nothing to do with SHEC objectives (or, the ‘level of protection’). TTIP discussions painfully demonstrate that many commentators are hardly or not at all aware of the WTO TBT agreement, which assumes SHEC objectives of national governments as given. It is all about instruments or red tape or avoidable duplications of tests, etc.

¹⁸ ENDS Europe DAILY (3 October 2014). See also Box 13.2.

¹⁹ “US-EU trade pact can cut import duties on €48 billion in chemical trade: Cefic”, *Platts*, 18 June 2013 (www.platts.com/latest-news/petrochemicals/london/us-eu-trade-pact-can-cut-import-duties-on-eur48-26030822).

might otherwise occur in their absence.²⁰ Greater collaboration and familiarity at the scientific level may eventually lead to building greater confidence in one another's regulatory approaches and that in turn could lead to further progress to reduce regulatory differences.²¹

4. Two decades lost? Missed opportunities for harmonisation?

Proponents of regulatory convergence in the chemical sector had higher hopes²² when the US and the EU announced that chemicals regulation would be a focus of the TTIP negotiations. TTIP came on the heels of nearly two decades of attempts to reduce the costs of mutual market access in chemicals through the Transatlantic Business Dialogue, as well as increased regulatory cooperation between the European Commission and the US Environmental Protection Agency,²³ and also broad-based efforts to harmonise chemical regulatory systems in developed countries more generally through the OECD.²⁴ The rationale behind all these efforts to reduce regulatory divergences was

²⁰ One study (Erixon & Bauer, 2010) estimates that eliminating tariffs on all products would boost EU exports by 7% and US exports by 8%. See also the comments of E.I. du Pont de Nemours and Company (2013): "Elimination of the remaining import duties on chemicals, currently averaging between 3-6%, would result in considerable savings to our company and remove many economic barriers to shipping technical and chemical intermediates." Francois et al. (2013) estimate that tariff removal only would boost EU chemical exports to the US by 5.4%; for US exports, it is no less than 12.4% (again, under the assumption of a 20% spill-over to 3rd countries).

²¹ Remarks of Jim Jones, Acting Assistant Administrator for the Office of Chemicals Safety and Pollution Prevention, US Environmental Protection Agency, "Towards a Transatlantic Market for Trade in Chemicals", 17 July 2013, Washington, D.C.

²² See remarks e.g. of Stuart E. Eizenstat (2013) in *E!Sharp*: "In fact, we should have confidence in the 21st century that the regulatory standards in both the EU and US are adequate to protect our publics and should be accepted, ... Mutual recognition is a sounder basis for regulatory cooperation than actual harmonization."

²³ For summaries of these precursors, see Quick (2007) and Shaffer & Pollack (2005, pp. 220-221).

²⁴ For example, see Box 13.1 and OECD Guidelines for the Testing of Chemicals (www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicals.htm).

succinctly summarised in a 2008 Congressional Research Service (CRS) report to the US Congress:

Since the mid-1990s, both US and European multinational companies have viewed divergent ways of regulating markets for both goods and services as the most serious barriers to transatlantic commerce. The primary reason why these companies seek to achieve greater harmonization in standards and regulatory procedures is to reduce costs imposed by complying with two different sets of regulations and standards.²⁵

The CRS report went on to opine: “Redundant standards, testing, and certification procedures are seen by [multinational] companies as far more costly and harmful than any trade barriers imposed at the border, such as tariffs or quotas” and that “[i]n no area has [regulatory divergence] been a greater problem than in chemicals”.²⁶

Hopes for progress on regulatory convergence received a boost in May 2012, when President Obama signed Executive Order 13609, Promoting International Regulatory Cooperation,²⁷ which declared the following as official US policy:

In some cases, the differences between the regulatory approaches of US agencies and those of their foreign counterparts might not be necessary and might impair the ability of American businesses to export and compete internationally. In meeting shared challenges involving health, safety, labor, security, environmental, and other issues, international regulatory cooperation can identify approaches that are at least as protective as those that are or would be adopted in the absence of such cooperation. International regulatory cooperation can also reduce, eliminate, or prevent unnecessary differences in regulatory requirements.²⁸

²⁵ Raymond J. Ahearn, “Transatlantic Regulatory Cooperation and Analysis: Background and Analysis”, Congressional Research Service Report for Congress, 22 October 2008 (<http://fpc.state.gov/documents/organization/112019.pdf>).

²⁶ *Ibid.*, pp. 2-3. This is consistent with the economic study conducted by Francois et al. (2013) for the Commission’s Impact Assessment of TTIP, finding that the costs of chemical TBTs are the second-highest (after automotive).

²⁷ www.gpo.gov/fdsys/pkg/DCPD-201200327/pdf/DCPD-201200327.pdf

²⁸ Executive Order 13609, §1.

Nevertheless, it is useful to recall that chemical regulatory cooperation was agreed to be reinforced following the New Transatlantic Marketplace in Madrid in 1995. As the survey by Quick (2007) describes in painstaking detail, *joint* US-EU business proposals by TABD were made, some of which were innovative. One might even call them bold! Without rehearsing the history in all its aspects, already in 1996 in Chicago, proposals were launched to follow up the OECD GLP and MAD agreements (see Box 13.2 in section 5) and negotiate Conditional Equivalence Agreements in a) risk assessment, b) notification of new chemicals, c) application and use and d) classification and labelling. Interestingly, the end point would be 'unconditional equivalence agreements' by 2000! Knowing that harmonisation was pointless, the TABD made a strong plea for forms of mutual recognition or acceptance as feasible alternatives. For instance, enhancing understanding and acceptance of methods used for hazard assessment and risk assessment was seen as a priority; exceptions for low-risk chemicals, polymers and R&D chemicals were favoured when registering new chemicals substances (to be fair, these suggestions were later echoed in REACH to some degree). For new polymers, an equivalence agreement (like mutual recognition) was proposed: once allowed to be sold in the US (EU), it could also be marketed in the EU (US). But Quick (2007, p. 255), complains that the "biggest obstacle to progress is the lack of understanding among the authorities concerning the other regulatory system". And, not to forget, REACH was in the early preparatory stages, which undoubtedly widened systemic divergence.²⁹

While misunderstanding of one another's systems is certainly an important factor, we also suggest an additional reason: the perception by key players that Atlantic regulatory cooperation is but an interim step towards developing chemical regulatory systems worldwide. Since REACH was proposed in 2003, if not before with the Chemicals White Paper in 2001 proposing the precautionary principle, Atlantic regulatory cooperation was throttled, if not in coma (except for very specific practical issues, case by case). Staking out positions for this larger game of defining the rules for trade in chemicals worldwide was more important to participants on both sides than the immediate gains that could be made by reducing differences in regulatory systems between the US and the EU.

²⁹ See Pelkmans (2005).

However, other factors also contributed to the failure of chemical regulatory cooperation between the EU and the US, including the politics of chemical regulation. As a practical, political matter in the current environment, making changes to REACH in Europe would have been extremely difficult and reform of TSCA has long been stalled in Congress. As this book goes to press, there is renewed hope that a bipartisan compromise may finally be reached in Congress to overhaul the outdated US Toxic Substances Control Act (TSCA), first enacted in 1976 and not significantly amended in the ensuing 40 years. However, from the EU end, the proposed changes are regarded as incremental: easier to regulate ‘restrictions’ but no comprehensive requirement for ‘registration’ (testing) of all chemicals before bringing them to the market³⁰ and no ‘authorisations’ regime for SVHCs on a company basis, and hence, only a little bit more ‘REACH-like’.³¹

There is a broad consensus in Europe and among academics in the United States that Section 6 of TSCA, which gives EPA authority to regulate chemicals analogous to ‘restriction’ under REACH, is currently ineffective. However, it is not always appreciated, particularly in Europe, that TSCA Section 6 is by its terms *only one* tool available to the federal and state governments in the US to regulate chemicals; indeed, by law EPA is supposed to regulate under (many) other statutes than TSCA if it can.³² Thus, the TSCA-REACH

³⁰ This should not be misread: for new chemicals, a PMN (= pre-manufacture notification) is required, but testing is not necessarily comprehensive (and not standardised a priori, as in REACH), depending e.g. on whether the substance is very similar to other ones known to be safe. Around one-third of the chemicals, for which a PMN is submitted, are *not* approved. For existing chemicals, no registration or testing is required and the burden of proof is on the EPA; here, the gap with REACH is wide.

³¹ See Kollipara (2015).

³² TSCA Sec 6, which is similar to ‘restrictions’ under REACH, only applies if the EPA lacks authority to address the risk under another statute. This limitation is explicit in the statutory language:

If the Administrator [of EPA] determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not promulgate a rule under subsection (a) to protect against such risk of injury unless the Administrator finds, in the Administrator’s discretion, that it is in the public interest to protect against such risk under this Act. In making such a finding the Administrator shall consider (i) all relevant aspects of the risk, as determined by the

comparison is far from a complete comparison of the effectiveness of chemical regulation as a whole. For this reason, Box 13.1 provides a primer on how the US regulates chemicals, as this seems too little known in Europe, and perhaps even in the US.

Box 13.1 A primer on how the US regulates chemicals

The US system for regulating chemical exposures is much more complex and multi-faceted than the one followed in Europe. This complexity is not necessarily desirable but instead reflects aspects of the US constitutional system and the incentives for US politicians to pass new laws for which they can claim credit rather than to amend or codify old ones.³³ In addition, US legal culture and traditions are more skeptical of government, resulting in the construction of multiple, redundant programmes.³⁴ The multiplicity of US laws and institutions does mean, however, that a simple-minded comparison between TSCA and REACH is misleading. TSCA is merely a last line of defence; by law, TSCA Section 6 authority can only be used if regulation under another statute would not be effective.³⁵

Administrator in the Administrator's discretion, (ii) a comparison of the estimated costs of complying with actions taken under this Act and under such law (or laws), and (iii) the relative efficiency of actions under this Act and under such law (or laws) to protect against such risk of injury.

15 USC. §2605(c), <http://www.law.cornell.edu/uscode/text/15/2605>

The EPA has generally found that addressing particular uses of a substance, e.g. in pesticides, foods, consumer products or releases to water, etc., is more effective than addressing it across the board under TSCA.

³³ For an account of 'competitive credit claiming' by politicians in creating US environmental laws, see Elliott, Ackerman & Millian (1985).

³⁴ This fundamental difference between the prevailing legal strategies in Europe and the US was noted by the sagacious European observer Walter Bagehot (1901) over a century ago: "The English constitution, in a word, is framed on the principle of choosing a single sovereign authority, and making it good; the American, upon the principle of having many sovereign authorities, and hoping that their multitude will atone for their inferiority."

³⁵ TSCA Sec 6, which is somewhat similar to banning or 'restriction' for particular uses under REACH, only applies if EPA lacks authority to address the risk under another statute. This limitation is explicit in the statutory language. If the Administrator [of EPA] determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not promulgate a rule

Numerous other statutory authorities and common law principles would have to be considered in order to assess the overall effectiveness of chemical regulation in the US versus Europe, and so far as we are aware, this has never been done.³⁶ For example, the standard West Publishing Company pamphlet of *Federal Environmental Statutes* lists 59 federal environmental laws alphabetically from the Acid Precipitation Act of 1980 through the Wood Residue Utilization Act of 1980, running to a total of 1,842 pages of small, 10-point type. About half of them apply to chemicals in various contexts. Add to these the administrative regulations in the *Code of Federal Regulations* (CFR) which are much more voluminous and detailed than the statutes themselves and the laws of the 50 states, which are generally allowed to add legal restrictions in addition to the federal ones in most fields.³⁷ And in addition, there are many other federal laws that regulate chemicals in various contexts that Americans do not consider 'environmental'. For example, the Occupational Safety and Health Act (OSHA)³⁸ regulates permissible exposure limits (PELs) for several hundred chemicals in the workplace.³⁹ Under the Federal Food Drug and Cosmetic Act, the Food and Drug Administration (FDA) has promulgated several short lists of chemical additives that are permitted for use in cosmetics, medicines and foods but bans all others unless they obtain special approval on a

under subsection a) to protect against such risk of injury unless the Administrator finds, in the Administrator's discretion, that it is in the public interest to protect against such risk under this Act. In making such a finding the Administrator shall consider: i) all relevant aspects of the risk, as determined by the Administrator in the Administrator's discretion, ii) a comparison of the estimated costs of complying with actions taken under this Act and under such law (or laws) and iii) the relative efficiency of actions under this Act and under such law (or laws) to protect against such risk of injury. See 15 C. §2605(c) www.law.cornell.edu/uscode/text/15/2605 and www.law.cornell.edu/uscode/text/42/7416.

³⁶ In the 1990s, one of the co-authors published a 97-page chapter in a treatise merely cataloguing the various federal environmental laws affecting the chemical industry, but did not purport to assess their effectiveness (see Elliott & Thomas, 1993).

³⁷ See e.g. Clean Air Act, §116, 42 U.S.C. §7416.

³⁸ 29 U.S.C. ch. 15 § 651 et seq.

³⁹ See 29 CFR 1910.1000, Tables Z-1, Z-2 and Z-3 (www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9992).

case-by-case basis based on test data.⁴⁰ The Consumer Product Safety Act (CPSA) regulates toxics in articles to which consumers may be exposed such as toys.⁴¹

Thus, the frequently quoted nostrum that REACH regulates 'articles' but TSCA does not, while literally true, is inherently misleading; TSCA does not regulate chemical usage in articles, but another federal statute does. Finally, one should not forget that the US is a common-law country. One of the reasons that TSCA has not been amended in 40 years is that many adaptations have been accomplished by judicial and administrative interpretation and practice, without ever codifying them in changes of the statute. Thus, the 'endangered species act' was converted from a statute protecting individual animals into one that protects biodiversity and critical habitat, without ever modifying the words of the statute. A somewhat analogous example of adaptation by administrative interpretation is the EPA's standard 'consent decree' for new chemicals (which comes closer to specific 'authorisation' under REACH) that a company agrees to restrict production, distribution and disposal of a new - presumably risky - substance until more knowledge becomes available.⁴² Its application is quite different from what the statute's drafters originally contemplated.

Yet another very different example is POPs (Persistent Organic Pollutants), which are chemical substances that persist in the environment, bioaccumulate through the food web and pose a risk of causing adverse effects to human health and the environment. Although the US signed, but never ratified, the Stockholm Convention, POPs are forbidden in the US in domestic legislation. In summary, the legal systems in the US and Europe are very different in their structure, which makes comprehensive comparisons difficult, but one thing is sure: counting the number of chemicals banned under REACH versus the number banned under TSCA is not an accurate measure of their differences.

⁴⁰ 21 CFR Parts 73, 74, 81 and 82 (www.fda.gov/ForIndustry/ColorAdditives/ColorAdditiveInventories/ucm115641.htm).

⁴¹ See Ed Loewenton, "CPSC Toughens Lead Regulations in Toys", 28 October 2008, describing provisions of the US Consumer Product Safety Improvement Act of 2008, §101 (<http://turnertoys.com/CPSC-Toughens-Lead-Regulations-in-Toys.html>).

⁴² See Renn & Elliott (2011, p. 237) describing "EPA's standard consent decree [under TSCA §5], which allows limited production and use of substances in specified uses with limited potential to cause harm while further information is developed".

One paper found that only a few substances had been regulated under TSCA, but conceded that at least 1,134 chemicals had been regulated under other US statutes as of 2011 (Schwarzman & Wilson, 2011, p. 109, Table 5.1). These statistics are old,⁴³ however, and do not even include de facto restrictive or chilling effects caused by tough US liability cases or voluntary withdrawals under EPA pressure. Schwarzman and Wilson went on to declare TSCA's ineffectiveness had created a 'data gap' and a 'safety gap' between the US and Europe. It is easy to count how many substances have been regulated under TSCA. It is much more difficult to assess the overall effectiveness of the US chemical control programme⁴⁴ and incentives created by common-law liability cases (see Box 13.1). In other words, there seems to be no ready, comprehensive and accessible information about the extent and level of protection against risky chemicals in the US, a remarkable circumstance to say the least.

There is very little literature comparing the actual breadth and stringency of regulation of chemicals in the US versus Europe on a systematic basis. There is, however, a widespread perception that REACH is more effective than TSCA and even if Congress ultimately does strengthen TSCA, it will require many years of implementation to build confidence in Europe that US regulation of chemicals is comparable to that in Europe.

The perceived differences between the effectiveness of regulation under TSCA and REACH may have been uppermost in the minds of the industry and the negotiators when drafting TTIP negotiation positions and we do not wish to be misperceived as discounting the importance of this factor. But in the long run, describing the politics of chemical regulation in the US and the EU at a particular point in time is less important than understanding the

⁴³ Note that Table 5.1 is based on rather old evidence by Dernbach (1997).

⁴⁴ Schwarzman & Wilson (2011) mention five such statutes: Clean Water Act, Resource Conservation and Recovery Act, Clean Air Act, Occupational Health and Safety Act and the Toxics Release Inventory of the Community Right-to-Know Act. As noted in Box 13.1, this is a painfully incomplete view of chemical protection in the US. At the same time, both the EU and the US have a lot of product-specific regulation of chemicals; in other words, also for the EU, there is much more than REACH (e.g. hazardous chemicals in electronic goods, end-of-life-vehicles, POPs, toys, food contact materials, etc.) A survey of 155 pieces of EU legislation, outside REACH, which may affect chemicals is in Milieu (2012).

dynamics of bilateral trade negotiations in the new era of globalisation of trade, and it is on that larger lesson that we focus.

5. Setting modest goals for TTIP

5.1 The joint position of the chemical industry and EU suggestions

Despite high hopes for greater regulatory convergence in the run-up to TTIP, substantive changes to the divergent regulatory systems for regulating chemicals on the two sides of the Atlantic were taken off the table even before the TTIP talks began, according to the position of the European negotiators that were leaked early in the process:

Industry associations, civil society and governments are aware that neither full harmonisation nor mutual recognition seems feasible on the basis of the existing framework legislations in the US and EU: REACH (Regulation (EC) 1907/2006) and TSCA (Toxic Substances Control Act) are too different with regard to some fundamental principles.

The recently completed REACH Review concluded that REACH should not be amended, while in the US a bipartisan proposal to amend TSCA has been introduced into Congress in May 2013.

However, the draft TSCA reform legislation does not foresee any general registration obligation for substances as a condition for their marketing (a fundamental requirement under REACH), nor elements comparable to authorisation, while it would give the EPA (Environmental Protection Agency) new and easier possibilities to conduct chemical assessments and adopt risk management measures such as restrictions.⁴⁵

This positioning rings true because, remarkably, the trade associations representing the chemicals industry on both sides of the Atlantic proposed a limited (joint) agenda that did not include making progress towards reducing non-tariff trade barriers in the form of duplicative regulatory reviews. A joint paper drafted by the European Chemical Industry Council (CEFIC), “with the cooperation of ACC,” the American Chemistry Council representing the US chemical

⁴⁵ These quotations are literally found in the EU’s position on chemicals, published a little later on the European Commission’s website (http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152468.pdf).

industry, outlined very limited “joint ACC-CEFIC proposals for enhanced cooperation in chemicals”:

- Common prioritisation principles and burden-sharing for assessments of high-priority chemicals and, where appropriate, categories of substances (e.g. substance evaluation under REACH and high-priority targeted risk assessments under the current TSCA and safety determinations under a modernised TSCA).
- Recognition of each other’s data and studies and harmonised standards and methodologies for hazard and risk assessment are necessary for effective burden-sharing.⁴⁶

The chemical industry’s joint position was that:

Closer cooperation on prioritisation of substances for further assessment would lead to cost reductions for both authorities and companies by creating opportunities for burden-sharing. That would also contribute to narrowing the difference in outcomes of assessments by fostering coherence and building confidence in each other’s assessments. *In the long run that could also result in greater coherence in regulatory outcomes including down-stream legislation which would further reduce regulatory divergence.*⁴⁷

Box 13.2 OECD accomplishments in chemicals regulatory cooperation

The OECD is usually regarded as fostering policy research in many domains, ensuring the quality of statistical series and economic studies in many fields and stimulating a wide range of cooperative and exchange activities amongst policy-makers. But it is not typically referred to as an agenda-setter or rule-maker. Yet, that is exactly what it has accomplished in chemicals, after decades of low-key technical work. Interestingly, the US and the EU have been leading in this work. When discussing regulatory convergence in chemicals over the North Atlantic, and even more so when suggesting that a gradual move to a common minimum of world regulatory requirements and methods in chemical risk management is so important for the EU and the US, one should first

⁴⁶ See CEFIC’s response to the European Commission’s request for further details on joint ACC-CEFIC proposals for enhanced cooperation on chemicals under TTIP, 7 March 2014 ([www.cefic.org/Documents/PolicyCentre/TTIP/%5bTTIP%5d%20cefic%20response%20to%20Commission%20ACC-efic%20proposal%20on%20TTIP%207%20March%202014%20\(web%20and%20click-in\).pdf](http://www.cefic.org/Documents/PolicyCentre/TTIP/%5bTTIP%5d%20cefic%20response%20to%20Commission%20ACC-efic%20proposal%20on%20TTIP%207%20March%202014%20(web%20and%20click-in).pdf)).

⁴⁷ Ibid. (emphasis supplied).

be aware of the achievements by the OECD. Alternatively, when assessing the current ideas of the negotiators in TTIP or, for that matter, of the chemical industry in their joint paper, the accomplishments of the OECD so far prompt the query: What value-added can the TTIP proposals really bring beyond the results of the OECD, quite apart from other – indeed higher – ambitions on chemical cooperation?

The OECD has generated three significant accomplishments. The most important one is the MAD system (MAD = Mutual Acceptance of Data). This is a *binding* agreement for member states based on an OECD Council Act from 1981.* The obligation is to accept chemical safety data from other OECD countries, plus seven other signatories (e.g. India, Brazil, South Africa, Singapore), if and only if these data have been generated using OECD Test Guidelines and OECD Good Laboratory Practices (GLP). The objectives of the MAD system is i) to save resources by avoiding duplication, ii) reduce NTBs, iii) reduce animal testing by acceptance of earlier testing and iv) arrive at a level-playing field for industry in if not beyond the OECD. The second accomplishment consists of agenda-setting for and follow-up actions in four types of OECD activity, all building on MAD: burden-sharing between countries on actual assessments of chemicals, such as the evaluation of safety of high-production-volume (HPV) chemicals; harmonisation of industry dossiers for chemicals and review reports for pesticides; exchanging technical and policy information; and outreach to non-OECD countries, crucial as the weight of chemical output in non-OECD countries rapidly increases. For instance, the ‘guidance documents’ for industry dossiers and reviews for pesticides (sometimes called a ‘monograph’) formulated ever since 1998 can be found in areas such as biocides, chemical accidents, regulatory oversight of biotech, safety of novel food and feed, and manufactured nanomaterials.

* There are two other OECD Council texts relevant for MAD. One is a Recommendation in 1989 on a range of practical implementation and enforcement issues of GLP. The other is a Decision of 1997 providing a step-wise procedure for allowing non-OECD countries to take part.

Source: Sigman (2013).

Conspicuous by its absence from the chemical industry’s ‘wish list’ is any mention of regulatory convergence or recognition of regulatory outcomes on either side. On the contrary, according to the chemical industry’s joint position, reducing regulatory divergence will have to await downstream legislation, because of differences in current legislation. The joint paper continues:

REACH and TSCA are very different with regard to prioritisation of substances for assessment and further risk management actions. Whilst TSCA applies risk-based prioritisation, REACH includes prioritisation based on production volume or hazard and, in several procedures, risk.

There are also substantial differences at later stages of the regulatory process, including ‘authorisation’ and whether government or the industry has the burden of producing safety information. It is interesting, and perhaps significant, however, that the joint industry paper emphasises the differences in the front end of the process, setting priorities. One even wonders how far beyond the useful but modest OECD chemical programme can TTIP move, with such a timid mandate (see Box 13.3). With the UN GHS being partly adopted inside the US (e.g. by OSHA) and the OECD programme working more or less reasonably well, should TTIP not go far beyond the mild aspirations of these intergovernmental organisations?

Box 13.3 Edging towards a draft text of the chemicals annex, EU suggestions

Following the EU position on chemicals (May 2014), the Commission published two so-called ‘non-papers’ in November 2014. In May 2014, it proposed ‘enhanced cooperation’ in four areas: i) prioritisation of chemicals for assessment and assessment methodologies; ii) promoting alignment in classification and labelling of chemicals, i.e. a full implementation of GHS in the US, which is a binding obligation – although without sanctions; iii) new and emerging issues, e.g. endocrine disruptors and nanomaterials; and iv) enhanced information-sharing, while protecting CBI (confidential business information). All these are useful but low-key approaches (in the words of the Commission, they “seek opportunities for cooperation exclusively in specific areas which do not require or imply any change in the regulatory systems of each side”). However, when no change in the systems and/or objectives is implied, one can do so much more to lower TBT costs. One ‘non-paper’ (http://trade.ec.europa.eu/doclib/docs/2014/november/tradoc_152912.pdf) is a first outline of how the Annex on chemicals in TTIP would look like. It repeats most of what is in the Position Paper, but adds a series of objectives, which do include (for the ‘living agreement’, one supposes) i) to “avoid unnecessary duplicative requirements” and ii) “to identify and implement actions that can lead to reduction of unnecessary

costs to transatlantic trade". Thus, in the longer run, a reduction of TBTs remains possible within the living agreement of TTIP.

Also, a Chemicals Working Group would be established, consisting of regulators. The second 'non-paper' (http://trade.ec.europa.eu/doclib/docs/2014/november/tradoc_152913.pdf) provides considerable practical detail on six areas of cooperation and how the US (usually, EPA) would be involved, step by step, in notice & comments and information (with an explicit call on the US to draft a similar non-paper for three of the six areas). These areas are: prioritisation of chemicals, i.e. updates of CoRAP under REACH, process for harmonised classification and labelling (which is already a UN standard, called GHS, but implemented in the US only by OSHA, so far; call on the US to develop a similar scheme for their NTP activities), nomination of SVHCs (very risky chemicals) for the candidate list of authorisation, prioritisation of SVHCs to be moved from candidate list to authorisation (Annex XIV REACH), involving the US when a restriction proposal (by ECHA or a member state) is listed in the Registry of Intent, and finally when companies (or consortia) submit applications for authorisation (e.g. link with alternatives based on EPA's Design for Environment Program).

These options cannot be belittled: no less than 22 different steps involving the US are identified for the six areas, implying numerous consultations, exchanges, comments and follow-ups between US and EU regulators. However, in TTIP one would assume the US to offer similar options, which would perhaps double the number of optional or obligatory interchanges between the two authorities. Where SHEC objectives are not that different over the North Atlantic, one should expect that quite often convergence or similar outcomes might finally be found. Although all this does not amount to a direct assault on TBTs, it is essential for building trust.

5.2 Backtracking by the European Parliament: 'Angst' or a sound case?

In July 2015 and without referring to the detailed proposals in Box 13.3, the European Parliament adopted a TTIP resolution which seems to turn against, or at least minimises, the chemicals negotiations in TTIP. The rationale of the negative attitude on chemicals is problematic. For this reason, we offer some further considerations on the hesitations of some European political actors. These considerations, however, are only partially based on public documents, as some actors are careful not to go public with their views. Therefore, the authors have weighed the drawbacks of relying on informal information obtained from

various discussions in the US and EU policy circuits, against the benefits for the readers of additional insights about the implications of these positions or interests. We have decided that the insights matter more, but the reader should judge.

A good deal of the nervousness or mistrust amongst some EU member state governments as well as some political forces in Europe, not to speak of some NGOs, is caused by the conviction that the US is suspected to have (hidden) hopes to be able to soften REACH or, seen as more likely, exercise 'regulatory chill' in the TTIP living agreement in subtle ways for future issues. This conviction may be right or wrong – there is no way of verifying⁴⁸ – but it is prompting a fairly defensive stance by the Greens and others in the EP, but also by some EU national governments (including, apparently, Germany). Asserting that, in future, TTIP might lead to 'regulatory chill' is a very poor 'argument'; in fact, it is not really an argument at all, it is a conviction driven by mistrust. In numerous trade and regulatory negotiations, all kinds of suspicions might be uttered, but should that be a reason not to negotiate?

More logically, the fear might be a reason to carefully draft agreements and rules, presumably. Moreover, what is 'regulatory chill' actually? Regulation has to be based on scientific risk assessment and subsequently solid impact assessment, as the Guidelines of the Commission help to do. If, and only if, risk assessment is not fully possible, as science cannot (yet) establish risks with acceptable degrees of probabilities, is there a choice of opting for the application of the precautionary principle. Is 'regulatory chill' meant to refer to TTIP possibly limiting the freedom to exercise this choice? Or is it a concern that joint work on the science might eventually persuade Europeans that their present approach is overly precautionary? But that is exactly what has to be specified in both horizontal and sectoral TTIP regulatory cooperation. Why would that be different for chemicals to such a degree that the EP should be so negative about it?

The present authors have difficulty understanding the logic of this defensive stance. Even if 'regulatory chill' might be regarded as a possibility, why would that be a problem for EU negotiators in TTIP now, or, later, in the living agreement? If US suggestions would be made having this effect, they would simply be dismissed and this is not

⁴⁸ US negotiators or involved officials have been tightlipped and no detailed documents, let alone proposals or positions, have been published by US Trade Representative.

new. Discussions with the US on REACH have been conducted for a decade or longer, in Brussels, Washington and indeed in Geneva (WTO) as well. Why would the Commission suddenly be incapable of properly pursuing a well-defined EU mandate or its specific manifestations? Can it be traced back to a simmering tension or distrust between those (more?) preoccupied with environmental and health matters and those primarily working on chemicals with industry and other chemicals found downstream in value-chains? The ‘angst’ for regulatory chill is found frequently amongst advocacy groups in Europe – it is a most convenient plank on which to campaign but it is purely assertive. It seems to reflect a sentiment that EU regulators and negotiators are too ‘malleable’ due to business pressures or simply soft negotiators. Given the record of the EU in many FTAs and in EU trade policy more generally, as well as in the international debate on REACH (including with the US), there is no rationale whatsoever to support this defensiveness.

Nevertheless, the European Parliament has, in its TTIP resolution of 8 July 2015,⁴⁹ stipulated that negotiators, when it comes to regulatory cooperation, should “recognise that, where the EU and the US have very different rules, there will be no agreement, such as on ... REACH and its implementation ... and therefore not to negotiate on these issues”. The possible problem of this formulation is not that REACH cannot be negotiated, as noted before: this was always clear and explicit, too. The additional words “and its implementation” constitute an attempt to exercise ‘cooperative chill’ due to plain mistrust. The ‘cooperative chill’ in TTIP on the ‘implementation’ of REACH imposed by the EP is of course a heavily-fought political compromise, or reflects an ‘exchange’ of give-and-take, in an already rather fragmented EP (with many parties) exhibiting several severe sensitivities with respect to TTIP. Moreover, it would appear to be inconsistent with several other paragraphs in the same resolution, also a regular phenomenon in EP resolutions. One can also query what the ‘implementation’ of REACH really refers to. The present chapter is not the place to analyse this question in-depth, but the giant REACH regulation cannot possibly be made to work satisfactorily by mechanical and pure ‘implementation’, as the resolution seems to suggest. REACH has and must have many processes which are governed by the overall objectives of REACH and disciplined by strict criteria, science for risk assessment and many other features, exercised e.g. by the Commission, ECHA, the member states and expert

⁴⁹ Under P8_TA-PROV(2015)0252 of 8 July 2015, para. 2. (c) (iii).

committees. The four elements in the EU's suggestions for chemicals in TTIP (Box 13.3) would not 'undermine' or negatively affect these processes. As noted, all four, in different ways, are discussed in international organisations, too. Does the EP fear that TTIP regulatory cooperation amounts to a duty-to-agree? This would be absurd. Does it fear that the involvement (mostly by comments and consultation more broadly) of the US will a priori exercise a chilling effect, or, lead to compromises that would be less ambitious than what the EU on its own would have decided (apparently this is what German government circles are afraid of)? But is it not true as well that, if TTIP would come into being, the EU could then exercise a similar influence in the US where chemicals are hardly less controversial than in the EU?

It is also worthwhile to discuss briefly three of the four suggestions in Box 13.3 (ignoring data-sharing). First on classification and labelling where the UN GHS has long been accepted by both the US and the EU (and many other countries). However, whereas OSHA in the US applies GHS, EPA does not. What is holding back the EPA from implementing a binding agreement that has the advantageous effect of lowering trading costs over the Atlantic and worldwide? It is said that this is due to pressures from leading pesticides companies (which include three European firms as well). Moreover, when applying GHS, one might attempt to harmonise further (e.g. in choosing the same classification for any given substance), but here the intricacies become greater. Why and when does the EU or US classify substance x as carcinogenic or not (and subsequently apply GHS)? Let us suppose that one would agree to apply a Vogel-type harmonisation-up and decide to always go for the highest classification on either side. On the face of it, this would rule out controversy. But there is a snag: the EU identifying x as a SVHC thereby automatically blocks its use in pesticides. Second, the prioritisation for the evaluation of chemicals (and methodologies) does not affect the decision how and how stringently one protects, in case the substance turns out to be risky. This cooperation is meant to cut costs for the two parties by sharing the burden. Of course, this does require regulatory cooperation and precise agreement, case by case or in agreed programmes, presumably based on the chemical annex in TTIP. To block such useful cooperation (aiming precisely at cutting needless duplication), on the basis of the EP resolution, is simply not sensible.⁵⁰ These are REACH processes that have to be pursued anyway.

⁵⁰ Paragraphs 2.(c)(v), (vi) and (viii) of the EP Resolution acknowledged this.

What one might suggest doing is that such (TTIP) programmes are first justified by scientific analysis in a report and discussed in the EP, so that trust is created. Third, 'new and emerging issues' such as endocrine disruptors (EDs) and nanomaterials has a scientific and a more judgmental or 'political' aspect. On the former, cooperation and burden-sharing seems eminently sensible in TTIP, OECD, WHO or indeed in all of them. On the latter, the EU has become quite prudent. For example, Commission Vice-President Frans Timmermans has decided to subject the draft delegated act on EDs, biocides and pesticides, which has passed its deadline for publication, to impact assessment, a sound decision in itself but mistrusted, by the same forces that are so sceptical in the EP, as a sign of unwillingness to extend the EDs list. For them it is a small step to suggest that this is 'due' to TTIP. These sensitivities are not a good reason to reject the option of regulatory cooperation on 'new and emerging issues' - not least because chemicals is a world market and derivatives in value chains can simply not be ignored. Nevertheless, one should exercise utmost prudence and make every attempt to build confidence-building measures rather than turn a blind eye to the problem. One may also want this issue to be shifted from horizontal regulatory cooperation to the specific chemicals annex where chemicals regulators govern the process.

The chemicals section of TTIP has been much less controversial in the US, with most of the concern focusing instead on the 12-nation Trans-Pacific Partnership (TPP), which has been characterised as America's "most ambitious trade deal since the North American Free Trade Agreement in the 1990's".⁵¹ Much of the political dialogue in the US does not distinguish between TTIP and TPP, but is opposed to free trade agreements more generally as weakening US regulatory protections.⁵²

⁵¹ Writing in the *New York Times*, Granville (2015) observes: "Opponents in the United States see the pact as mostly a giveaway to business, encouraging further export of manufacturing jobs to low-wage nations while limiting competition and encouraging higher prices for pharmaceuticals and other high-value products by spreading American standards for patent protections to other countries. A provision allowing multinational corporations to challenge regulations and court rulings before special tribunals is drawing intense opposition."

⁵² In a posting on *techdirt.com*, a blogger quotes from a press release from the Sierra Club: "Governments must take a page out of the history books and stop

6. Contrasting REACH and TSCA: Perceptions and critical assessment

6.1 Why both are criticised?

Curiously, there is resistance against TTIP chemicals negotiations going deeper both from the two sides in the negotiations *and* from NGOs. The position of business (CEFIC and ACC together) is accommodating this resistance by not offering an alternative view, but merely a useful, yet cautious preparatory route. From a trade-policy point of view, this is peculiar because the costs of TBTs in chemicals trade over the North Atlantic are amongst the highest of all industrial sectors. Lowering these TBT costs drastically would probably yield large economic gains. It is thus disappointing that the chemicals TTIP chapter does not reflect the original spirit of the partnership and is not more ambitious in focusing on removing or minimising TBTs.

Can one understand this resistance from a regulatory point of view? Yes and no. No, one cannot, once one is willing and capable to assume a more rational and detached analytical view of how EU-US chemical regulation *should* be designed. Yes, one can, if one joins the many stakeholders and officials of the chemical policy-making communities on both sides, repeating all the time that the two regulatory regimes are too divergent. Nobody seems to ask the more relevant question whether the one or the other regime, or both, embody ‘good regulation’, applying GRPs (Good Regulatory Practices). And, as a corollary, whether, if GRPs were applied on both sides, the ‘divergence’ would shrink with it. ‘Better regulation’ would yield additional economic welfare, and if its application would indeed also shrink the divergence, TBTs would be much lower, too: a clear *win-win*. It is fairly obvious that both chemical regulatory regimes can be improved and a mutually compatible and sound way of doing that is to employ ‘Better Regulation’ principles, most of which have long been agreed transatlantically!⁵³ Since the very purpose of TTIP is to reap economic

negotiating trade pacts that cut protections for our air, water, land, workers, and communities” and adds: “That last comment is a clear reference to TPP, but applies equally to TAFTA/TTIP” (see “US Free Trade Agreements Are Bad Not Just For The Economy, But For The Environment” at: <https://www.techdirt.com/articles/20131022/10231424967/us-free-trade-agreements-are-not-just-bad-economy-environment-too.shtml>).

⁵³ See e.g. Quick (2008a). See also US-EU High Level Regulatory Forum (2011) and Chase & Pelkmans, ch 2 in the volume.

gains and, as a subsidiary goal, to set proper world standards for good regulation benefitting everybody, why is such beneficial regulatory reform not embraced and pursued?

Both chemical regimes are criticised, but for very different reasons. Rightly or wrongly, the TSCA is mainly criticised for not addressing existing hazardous chemical substances that meanwhile are asserted, feared or found to be of 'serious concern' and are or may soon be forbidden or restricted in other countries, including EU member states. In short, the TSCA is said to suffer from '*under-regulation*': a number of sensitive, risky substances are said not to be tackled and the tools and intervention options for the EPA are too restrained. As Schwarzman & Wilson (2011) call it: TSCA generates a 'data gap' and a 'safety gap'.⁵⁴ How true this is remains unclear. There are isolated examples like asbestos,⁵⁵ but can one generalise?

REACH, on the contrary, is said by many to suffer from '*over-regulation*': it supposedly imposes unreasonably heavy and costly means in order to ensure the availability of quite demanding data on the possible hazards of each and every substance above 1 tonne per year, for presumably some 30,000 substances, including complicated information and interaction flows up and down the value chains. There is no clarity at all whether or not all this data is 'needed' or even 'read' by regulators (despite their high costs) except in a limited number of instances. None of this directly supports health, safety and the environment, but some of it might, later on; the latter is all to be ensured in a lengthy second set of procedures of REACH, to wit, evaluation, authorisation and (new?) restrictions. The costs of the first stage (registration) now begin to be better estimated and they seem to be roughly double what was already seen as very high upfront costs in the constitutive days of the Regulation. This would imply some €4-5 billion costs for registration and what it takes, alone.⁵⁶ Nobody has any clue

⁵⁴ They also mention a technology gap, the lack of incentives under the TSCA to invest in 'green chemistry'.

⁵⁵ Note, however, that the EPA banned asbestos in 1989 (54 Fed. Reg. 29,460), but this regulation was set aside by the courts in *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201 (5th Cir., 1991). Later, under pressure from EPA to re-regulate, manufacturers in the US entered into an agreement to take asbestos-containing products off the market.

⁵⁶ The 2003 Impact Assessment of REACH estimated some €2.3 billion of upfront costs (direct costs for registration, mainly testing), some €1.1 billion of which would materialise in the early stage. The CSES (2012) review report of

about the eventual benefits later on.⁵⁷ By definition, these direct costs are not justified by the benefits because the latter cannot possibly be known even in a very crude estimate. The costs are only ‘justified’ by a *wholesale* application of the precautionary principle (PP) to *all* chemical substances known (above 1 tonne). Note that these costly testing and registration requirements are not just applied to several thousands of substances about which a suspicion might exist but not ‘enough’ scientific evidence has been generated – then pre-caution makes sense and testing and research seem justified (if possible, proportionately).

However, the idea is that one applies the (often-costly) PP to many thousands, indeed tens of thousands, of chemical substances, without having a clue whether that application is in any way justifiable in most of these tens of thousands of cases. This is surely *not* in keeping with the avowed notion of that principle, as elaborated e.g. in the famous European Commission (2000) paper on the Precautionary Principle. Application of PP requires there to be ‘insufficient’ knowledge about risks, in other words, there have to be *some* compelling but as yet ‘insufficiently’ certain or clear risk indicators. If the PP requires a recognition of ‘insufficient knowledge’, it follows directly that it cannot be applicable when there is no risk by any sign or indication. The PP may be justified, as historical examples of instances in which governments failed to act upon early signs of trouble may suggest,⁵⁸ in instances where there are indications via victims and other possible evidence of harm as well as early signals in research, without being sure. However, severe and irreversible damage might be caused and a temporary PP application can be defended (e.g. BSE should have been dealt with PP at an earlier stage).

The PP may ‘be better safe than sorry’, but it also brings with it the risk of false positives and excessively heavy intervention. Assume,

REACH (for the Commission) reports instead a ‘mid-range’ amount of €2.1 billion. With the big wave of numerous small-volumes registrations driven by SMEs in 2018 still ahead, and assuming a similar underestimation in 2003 for this wave, it further estimates that one would arrive at direct costs of some €4.5 billion.

⁵⁷ Note that, even if some benefits would be identified under ‘better regulation’ principles, this is not necessarily convincing, as – possibly – the same benefits might have been found with a far less-imposing system. As in impact assessment, one always has to think in terms of alternatives.

⁵⁸ See EEA (2001); a second report (“Late lessons from early warnings: Science, precaution, innovation”, was published by the EEA in 2013: www.eea.europa.eu/publications/late-lessons-2).

for example, that of the 30,000 existing substances (from 1981), there are no signs of hazard in 25,000 instances, perhaps even more; some others suggest that a 40% benchmark would be safe, implying that 18,000 need not be investigated at all. The point is that one cannot credibly assert that all or nearly all substances pose dangers for inflicting harm on consumers or workers. Many of these substances have been around for a long time and, in many cases, there are no suspicions whatsoever. Why the PP would have to be applied in a heavy way, or at all, for all *other* substances as well, merely on the criterion of tonnage, is still in need of justification. One may call this objection 'risk-based' – and indeed, it is – but it is just as much a *proper* application of PP. In the absence of any sign or indicator of risk, why impose such costs?

It is, however, possible to assume a slightly more cautious position, with some justification, when observing that the C&L (classification and labelling) Inventory does comprise many substances with hazards (not necessarily risks, as exposures might be minimal). The authors have been informed that some 120,000 substances in the inventory have been classified with at least one hazard. Thus, it should be possible to develop a proportionate system, where substances (not known to carry a risk) could be subject to an alert system followed by testing, when there would be any reportable sign of this hazard having turned into a risk. That would reflect the spirit of PP.

In all likelihood, there are now huge costs to registration in REACH, especially for SMEs,⁵⁹ and no or next to no societal benefits anywhere on the horizon for the very large majority of substances. That is 'over-regulation', indeed, uniquely costly over-regulation, because of the wholesale application of PP to registration via tonnage (rather than risks or even a sign of it) and the separation of a lengthy trajectory of incurring costs (costly testing and data collection) from the search of societal benefits. There is a better case for demanding data collection for the registration of 'new' substances, but even here sophisticated forms of pre-selection of what might constitute hazardous chemicals would seem to be possible, underpinning a more targeted approach (as noted, some exceptions accepted by REACH do reflect this approach). These considerations carry over to different perspectives on priority setting for new chemicals, discussed in section 9.

⁵⁹ See Pelkmans, Schrefler & Gubbels (2013) for worrying mid-range evidence.

6.2 What we do not know about ‘divergence’?

One can also argue, that in the final analysis, what matters for improving safety, health and the environment – the societal benefits – is the overall effect of the legal system as a whole in banning, restricting or (targeted and restrictedly) authorising specific substances, or their uses. The critical question in TTIP is not whether the legal procedures of the two regimes are so divergent, but whether they are good (enough) *in delivering the desired societal benefits*. To be more precise, how comparable are the bans, restrictions and (what in REACH is called) authorisations referring to the same substances on both sides of the North Atlantic? One would expect some divergence there because the TSCA (combined with other US federal laws on food, pesticides, etc.) might be ‘under-regulating’ (i.e. not all market failures are overcome), but it seems not so easy to establish firmly how severe that ‘divergence’ is. Moreover, the effects are not uniform in all areas. In some areas (such as suspect carcinogens in diesel exhaust, e.g.), the US tends to regulate more stringently than in Europe, whereas in others (such as suspected endocrine disruptors), Europe regulates more stringently. The authors have not been able to find authoritative evidence on the specifics of this divergence, let alone on how ‘wide’ it really is. Adding up REACH (where four authorisations have been made so far⁶⁰ and several hundreds or more restrictions⁶¹ exist at the moment), some remaining chemical directives, pesticides and cosmetics regulation (prohibiting animal testing, unlike the US), the EU has probably banned or restricted more substances than the US, but that remains a conjecture. Ultimately, it is this *factual* divergence in some sensitive substances regulation, but

⁶⁰ On 5 July 2015, the REACH Commission website listed four substances with an authorisation decision having appeared in the EU Official Journal, and a total of eight substances, with a range of applications, “pending adoption”. There are 166 substances on the candidates list.

⁶¹ On 11 July 2015, the ECHA list of restrictions (<http://echa.europa.eu/addressing-chemicals-of-concern/restrictions/list-of-restrictions>) identifies 64 restrictions in categories of substances, with subdivisions, totalling altogether 105 entries. Note that this list includes Annex XVII of REACH and ‘old’ restrictions under the former Directive 76/769/EEC. Another five restrictions are under consideration. However, the total of 105 does not relate to individual substances only; thus, entries no. 3, 28, 29, 30 and 40 refer to classes of substances (e.g. carcinogens, mutagen categories, flammable gases, liquids, solids, etc.). Moreover, quite a few entries refer to families of substances with the same name (e.g. azocolourants and azodyes). Any comparison with the US would thus have to carefully specify the individual restrictions on both sides.

more importantly the *overlap* of substances regulated both by the US and the EU, that matters for SHEC regulation and society. And it is this area of overlap where much more constructive and innovative transatlantic approaches could be proposed and scrutinised. Even if the overlaps were few and far between, say 'mere islands of convergence in a vast sea of divergence', the places where the two parties can come together are what is important for trade agreements. Later we propose a system whereby such areas of similar or mutually acceptable levels of regulation can be identified and unnecessary trade barriers gradually eliminated over time.

7. Carved in stone: REACH and TSCA suffer from excessive rigidity

7.1 REACH immobilises

In order to conduct fruitful TTIP negotiations in chemical regulation and trade, reform of both regulatory regimes would be very helpful. However, these reforms do not 'need' TTIP; such reforms are justified in their own right. Reforms have a double rationale: i) both systems would be much improved if subjected to 'better regulation' principles, and ii) reforms should facilitate TTIP to generate major economic gains. This recognition has emerged in the US, but until recently, it has been hard to organise a winning, bipartisan coalition in Congress, leading to repeated delays up until today in reforming TSCA. One might also wonder how 'deep' the reform would be. But such a recognition is lacking in the EU. REACH has become a sacred cow! Alas, for the wrong reasons. Although the design of REACH is heavy and overly costly, especially in its processes, mainly due to the wholesale application of PP to registration (with demanding data) of all chemical substances, it is treated as 'untouchable'. A steady flow of criticism from e.g. SMEs among others, is answered either with marginal or symbolic responses or neglect, or legal defences are formulated without ever reacting to the core of the issue.

There would seem to be two reasons why REACH has become a sacred cow, thereby incurring unnecessary burdens for EU industry and ultimately the supply chain and possibly consumers, and, in addition, making meaningful TTIP negotiations more difficult or reducing them to modest features. First and foremost, it is about the very long duration of the implementation process. The official position is that the process will take 11 years, until 2018 inclusive, when small-volumes registration will take place. That is an extremely long period

during which EU bodies are in the frustrating position of having to implement, process and enforce numerous measures, without being able to change the legislation (only some annexes in modest or purely technical ways). This is a direct consequence of the design of the REACH Regulation, with its highly principled and wholesale approach of requiring very demanding data for all chemical substances and uses, as discussed before. But now that the REACH obligations are enshrined in EU law, SMEs cannot be treated on a more sensible and far less-costly risk-basis for (say) 2018, as this would be regarded as discriminatory for all earlier registrations. REACH has stifled any initiative or even any serious debate on switching REACH towards a more risk-based approach, which need not and should *not affect any eventual societal benefit* but greatly reduce private costs (and to some extent public costs).

As a result, a 'deep' TTIP approach in chemicals is doomed not to touch the instrumentalities of registration (no data, no market), which constitutes a big TBT where substances do not have any risk indication. Also, the communication over the value chain, often two-ways and costly,⁶² is just as valid for US exporters as for EU-based producers and users, irrespective of whether the substances are suspect or not. The REACH system now governs the TBTs as given, indeed, carved in stone, even though precisely this instrument – not a 'level of protection' – should be at issue! In other words, the very long duration of REACH implementation creates an excessive form of rigidity that is immune to sensible calls for flexibility or amendments made in Europe, let alone, for reasons of 'deeper' TTIP negotiations or sensible REACH reform.

One might perhaps entertain some hope that TTIP, as a 'living' agreement, might be able to address such issues after 2018. However, and this is the second reason, by 2018, REACH will only be relatively early in the complementary stage of going through heavy and time-consuming authorisation procedures, and possibly new restrictions. The original idea behind authorisations was that SVHCs would be identified – and not known before or now better understood – so that substitution could be stimulated and 'temporary permissions' be given to companies using the SVHC. An outer bound of the expectation is the infamous SIN (Substitute It Now) list put together by the NGO community. As is well known, the candidate list of SVHCs, being continuously filled up with substances for authorisation, has an immediate chilling effect in markets (including value chains), although

⁶² See CSES (2012) and Pelkmans, Schrefler & Gubbels, (2013).

the whole point of the authorisation procedure is precisely to verify risk in-depth and subject the production and use to a careful societal balancing procedure.

In any event, an outer bound would be that the EU would end up with the SIN list of 300-minus substances. Yet, this would then have taken a decade or more of authorisation procedures. And the SIN list is a mere 1% of existing substances under REACH (if the 1981 inventory is taken). However, that list was already made up in 2007,⁶³ when REACH had not even begun. If the SIN list were so clear, and if market players do regard it as critical for their reputation, why the huge data requirements for *all* substances over no less than 11 years? And why all these heavy procedures for many years more? Most restrictions actually pre-date REACH. However, these expectations are now in doubt. It is suggested in REACH circles that authorisations will be generated for decades to come, as data (including new data) may well prompt demands from member states to verify the SVHC nature of ever-more substances. Clearly, if this is true, it is of utmost importance that the US and the EU cooperate on the prioritisation of substances and try to reach convergence on when, and based on what criteria, a risk renders a substance a SVHC.

TTIP in chemicals is perhaps doomed to stick to negotiating the forms of 'regulatory cooperation', as mentioned in Box 13.3. The 'frozen' attitudes on both sides, working from two instances of regulation subject to improvement (that is, not applying Good Regulatory Practices), and with regulators not in a position to question the instruments of the regimes – the objectives are not at issue – even when the arguments are convincing, are inconsistent with the very aims of TTIP: higher economic welfare, that is, ensuring societal benefits (overcoming SHEC market failures) with the lowest costs possible. The high TBTs in chemicals trade are a direct consequence of two regimes being subject to significant improvement; their 'divergence' is largely a consequence of their absolute immobility.

⁶³ The SIN list is a collection of SVHCs as identified by the NGO Chemsec (see <http://chemsec.org/what-we-do/sin-list>). Last updated 8 October 2014, the total list includes some 800 possibly harmful chemical substances, but some 300 are now claimed to be SVHCs (by Chemsec). The list is not considered fully reliable from a scientific point of view.

7.2 Is the US incapable of ‘harmonising up’?

One could also argue that the challenging question is not why Europeans would want to hang on to the perceived benefits of REACH, but why Americans would not want to use TTIP as an opportunity to ‘harmonise up’ to the system that the EU and many US academics and NGOs perceive as superior.

The prevailing academic understanding of bilateral trade talks was defined in the mid-1990s by David Vogel in his influential book *Trading Up*.⁶⁴ Professor Vogel studied a series of trade negotiations in the 1980s and early 1990s, including the North American Free Trade Agreement (NAFTA) between the United States, Mexico and Canada and concluded that ‘harmonisation up’, adopting the more stringent standard for mutual gain, was nearly inevitable in trade talks, provided that certain minimal conditions were satisfied. Vogel called this the ‘California effect’, a term that seems somehow quaintly parochial by the standards of today’s more international discourse,⁶⁵ but by which he meant a race to the top rather than a race to the bottom:

Trade liberalization is most likely to *strengthen* consumer and environmental protection when a group of nations has agreed to reduce the role of regulations as trade barriers and the most powerful among them has influential domestic constituencies that support stronger regulatory standards. Thus, the stronger the commitment of nations to coordinate their regulatory policies, the more powerful is the California effect [i.e. race to the top rather than the bottom]. Likewise, the weaker the institutions created by regional or international trade agreements on treaties, the weaker the California effect.⁶⁶

Vogel’s model is a simple one: each trade negotiation is imagined as a discrete single-play game between two players about a single regulatory issue; each side believes that it will benefit to some extent from the increased exchange that comes from reducing trade barriers, including non-tariff barriers from divergent regulatory systems. If more stringent regulations on one side are sufficiently supported by a

⁶⁴ See Vogel (1995).

⁶⁵ However, an interesting elaboration of the interaction between Californian regulation and EU regulatory thinking is found in Vogel & Swinnen (eds) (2007); in Vogel’s later work, he demonstrates a U-turn for the EU becoming more and the US less precautionary. See Vogel (2012).

⁶⁶ *Ibid.*, p. 8.

domestic political constituency so that adopting them is a condition for obtaining the benefits from greater exchange, the more stringent regulation will be adopted by the other side, Vogel argues, provided that the costs of doing so do not exceed the anticipated benefits of getting a deal. Thus, according to Vogel, the greater the perceived benefits from reaching agreement, the greater the 'California effect' of inducing regulatory laggards to come up to the higher standards of their trading partners. The game becomes more complicated, and more realistic, if more than a single regulatory issue is subject to negotiation, so that trading one issue off against another becomes possible, but the logic is essentially the same: parties will agree to more stringent regulatory standards where the benefits from increased trade are greater than the costs from more stringent instruments of regulation.

From the standpoint of Vogel's model, harmonisation of chemical regulation through TTIP should have been an easy case: Europe's REACH programme is generally perceived as more stringent than US regulation under TSCA, at least in the sense of having higher compliance costs.⁶⁷ As described in more detail later, most of these extra costs are not a result of setting more constraining standards for exposure to substances that are regulated. Indeed, indications suggest that *actual* regulatory levels are remarkably similar in both systems, although far more precision on this point is desirable. Rather, the higher costs of compliance with REACH are due primarily to two factors: i) higher costs of compliance for preparing dossiers of health and safety data for all chemicals above certain production limits, whereas TSCA uses a much more targeted approach in which health and safety data are required for only a very small subset of chemicals, and until recently, none for *existing* chemicals that were already on the market when the law was enacted in 1976; and ii) some substances that are regulated in Europe are not regulated in the US, and vice-versa.

⁶⁷ For an argument that a regulatory system is not necessarily better merely because it imposes higher costs of compliance, see Renn & Elliott (2011). Moreover, according to Elliott & Elliott (2009), "a legal system is not necessarily 'ahead' merely because it stimulates a greater degree of precautionary behavior by those it regulates. Rather, the proper question is whether a legal system is achieving the degree of precaution that is deemed appropriate under the circumstances. Too much precaution, as well as too little, may have both costs and benefits, in terms of useful products or innovations that are needlessly not marketed."

Why didn't the US side simply agree to adopt a more REACH-like system, at least for those substances that are already regulated by both the US and the EU, as predicted by Vogel's model? One obvious answer endogenous to Vogel's model could be that the perceived costs of adopting REACH on the US side were greater than the expected benefits from harmonisation. In a sense, the conclusion that perceived costs were greater than perceived benefits is tautological: there must be some rational reason why the negotiators were unwilling to 'trade up', as Vogel predicts they would.⁶⁸ But exactly what were the perceived costs of adopting REACH (or a more REACH-like compromise) on both sides of the Atlantic, and why were these costs thought to be greater than the benefits of harmonisation?

The puzzle becomes even more interesting when one realises that virtually all of the extra costs of complying with REACH are (once and for all) 'sunk costs' that have already been paid by many US-based chemical companies, because many of the chemical companies operating in the US also either sell some of their products in Europe or someone else who does sell that substance in Europe has already registered it under REACH and hence they have already been required to comply with REACH, at least for existing substances. Rational economic actors are not supposed to consider sunk costs, that are behind them, in making decisions about what is best for the future, although we know that sometimes people (and possibly even companies and nations) do not always behave 'rationally', as predicted by neo-classical economic models.⁶⁹ It is also theoretically possible that the additional economic costs of complying with a REACH-like system in the US for new substances not already regulated under REACH were perceived to be greater than the perceived trade benefits from harmonisation, although we think that is unlikely, in part because US chemical companies frequently supply to the large European market. Even for substances that will be developed in the future, they must anticipate that they are going to have to comply with REACH.

⁶⁸ See generally Leff (1974), who points out that the 'discovery' that the people often act to maximise perceived benefits and reduce costs is nominalism.

⁶⁹ "Behavioral economics recognizes that sunk costs often affect economic decisions due to loss aversion: the price paid becomes a benchmark for the value, whereas the price paid should be irrelevant. ... Economic experiments have shown that the sunk cost fallacy and loss aversion are common, and hence economic rationality — as assumed by much of economics — is limited." "Prospect Theory" Kahneman & Tversky; For an accessible summary, see <http://youarenotsosmart.com/2011/03/25/the-sunk-cost-fallacy/>

A simpler answer to why the US is not capable of ‘harmonising up’ might be the pressure from US industry not to accept REACH’s costly general registration requirements (with demanding data-development obligations) for existing chemicals and instead to accept – but also limit – new powers for restrictions in a reformed TSCA.

8. Spill-overs and a world regime?

8.1 Positive spill-overs with or without TTIP

Our off-the-record interviews with participants lead us to conclude that regulatory convergence was taken off the table early because both sides perceived TTIP not as an isolated single-play game (as Vogel’s model implicitly assumes) *but rather as a step in a larger process of defining the rules for commerce in chemicals in a rapidly-globalising economy*. Neither side was willing to give up its position on what should be the emerging worldwide system of chemical regulation in order to obtain the immediate benefits of harmonisation through TTIP. The important, and generally overlooked spill-overs from the TTIP negotiations, are described by Lejour et al. (2014) as follows:

The CEPR study [Francois et al., 2013] on the TTIP briefly deals with the spill-over effect to third countries, following the lowering of regulatory barriers between the US and the EU. These spill-over effects would not emerge if two small countries form a FTA, but this is different once the two largest economies in the world cooperate on regulatory issues. Direct and indirect spill-over effects are positive for 3rd countries and can be modelled. Direct spill-overs improve the trade possibilities of third countries with the EU and US without any further action on the part of 3rd countries – they are automatic. If the EU and the US streamline their regulatory procedures, this is subject to most-favoured-nation treatment (MFN) under the WTO and it becomes also easier for firms from other countries to export to the US or the EU. ... It makes sense that firms in other countries adopt the regulatory standards of large countries, when the former are closely linked to the EU, the US or both. This would also improve market opportunities for American and European firms in these third countries. ...

Of course, the greater the spill-overs to 3rd countries, the more TTIP outcomes begin to look like multilateral or plurilateral - rather than bilateral - results benefitting all. This important significance is further enhanced by the

consequence that also TTIP itself would see its gains enlarge due to such spill-overs.⁷⁰

This type of argument focuses primarily on the optimistic case in which the US and the EU reach agreement on a harmonisation approach, where “the two largest economies in the world cooperate on regulatory issues”. What they did not analyse until now is the other side of the decision tree of how spill-overs from TTIP may play out if the two sides do NOT agree on regulatory convergence.

Many countries around the world are now developing their own national system for regulating chemicals. In October 2010, REACH-style legislation came into effect in China to regulate the environmental risk and hazard of China's new chemical substances, under the Ministry of Environmental Protection (MEP) Order No. 7. Called Measures for the Environmental Management of New Chemical Substances, this regulation comprises notification requirements for new chemicals and catalogues hazardous chemicals among existing ones, but it hardly follows REACH principles despite elusive suggestions to the contrary (leading to the nickname ‘China REACH’).

South Korea has also developed its own regulatory system, called K-REACH, which went into effect 1 January 2015.⁷¹ K-REACH was more explicitly “designed to closely mirror REACH”⁷² (in a more risk-based and proportionate form). Other countries such as India, Thailand, Australia, Malaysia and Turkey are also reportedly developing their own national systems. Indeed, if the EU and the US were to reach agreement on a common approach to regulating chemicals, it would be hard for other countries to ignore their shared approach, as the combined EU-US market is the largest in the world,

⁷⁰ Much the same point was also made by Daniel Hamilton, co-director of the CEPS/CTR project on TTIP, in his public remarks in Brussels on 9 April 2014, when the present project was announced. Hamilton observed that if the EU and the US were able to agree on their higher standards for protecting environment, safety and workers, these standards would become the de facto international standards going forward as opposed to lower “Asian standards.” Hamilton argued that the benefits to the EU and US of setting the bar higher far outweighed the small differences between the two.

⁷¹ See the website dedicated to Korea's own regulatory system for chemicals (www.thereachcentre.com/site/content_south_korean_chemicals_info.php).

⁷² Ibid.

particularly for chemicals.⁷³ But what happens if the US and EU do *not* agree, but instead maintain their divergent approaches?

From the European side, Europe might well gain a trade advantage vis-à-vis the US if other countries adopt REACH-like systems, because European companies would be more familiar with REACH requirements in Europe and would not have to bear the costs of duplicative regulation in other countries. The European Union is quietly promoting the REACH model to other countries. On the US side, US chemical companies maintain that they are not yet ready to concede that REACH represents the future of chemical management worldwide. They still hold out hope that more targeted approaches, represented by the Canadian Chemicals Management Plan (CMP),⁷⁴ and pending TSCA Reform legislation may prevail over the long run as the model for a harmonised international system.

8.2 US industry objections against REACH

The essential difference between the Canadian Chemicals Management Plan (CMP) and REACH is that under the CMP, experts agree in advance on high-priority substances and only require submission of test data for those substances. Proposed bipartisan amendments to TSCA that are supported by industry in the US adopt a similar approach, in which the Environmental Protection Agency (EPA) would conduct rule-making to categorise substances as either ‘high risk’ requiring further analysis, or ‘low risk’ so that they can be marketed without further studies.⁷⁵ This carries forward to *existing* substances in the current approach of the TSCA ‘pre-manufacture notification’ programme, under which EPA uses predictive techniques, such as computer models and ‘structure activity relationships’ (SARs) or

⁷³ According to Eizenstat (2013), “The EU and US together account for almost half of global output of goods and services and almost a third of global trade – almost \$1 trillion annually.” Specifically for chemicals, the 2012 domestic sales in chemicals of the US and the EU amounts to one-third of total global sales, with China alone having another one-third. In terms of world exports of chemicals, the US and the EU hold 40.5%, with China enjoying 14.3%.

⁷⁴ For a description, see <http://chemicalsubstanceschimiques.gc.ca/plan/index-eng.php>

⁷⁵ §4(a), Chemical Safety Improvement Act, S. 1009, 113th Congress, 1st Session, (<https://beta.congress.gov/bill/113th-congress/senate-bill/1009/text>).

'quantitative structure activity relationships' ((Q)SARs⁷⁶) to predict whether substances are likely to be hazardous *in silico* (i.e. through computer simulations) rather than requiring animal or other test data. Moreover, pathway-based toxicological testing in cell lines is thought by many to be the future of toxicology.⁷⁷

Many US companies believe it is unnecessarily wasteful to require comprehensive testing for all substances if science can target limited resources on substances that are most likely to cause problems. There are also independent critical voices. One of the present co-authors has written:

The new REACH program in Europe requires private parties to submit enormous reams of data about the safety of chemicals to a new government agency. In our view, one fatal flaw in programs such as REACH is that its drafters appear to imagine that sufficient analytical resources can be marshaled at the governmental level to conduct all of the risk assessments that need to be conducted in a complex industrial society. We believe that this assumption is incorrect, and that the overwhelming majority of the data assembled at great cost by industry in response to the REACH program will remain unread in government files.⁷⁸

One key difference between REACH and the US/Canadian approach is that under REACH, prioritisation occurs *after* data submission in terms of what dossiers will actually be reviewed by government as opposed to prioritisation in the US and Canada *before* requiring data to be generated and submitted. But it should be noted

⁷⁶ For an explanation, see <http://ihcp.jrc.ec.europa.eu/glossary/q-sars-quantitative-structure-activity-relationships>

⁷⁷ See generally Committee on Toxicity Testing and Assessment of Environmental Agents (2007), National Research Council, "Toxicity Testing in the Twenty-First Century: A Vision and a Strategy". In a brief accessible summary, the US National Academy of Sciences (http://dels.nas.edu/dels/rpt_briefs/Toxicity_Testing_final.pdf) writes: "The report envisions a new toxicity-testing system that relies mainly on understanding 'toxicity pathways' – the cellular response pathways that can result in adverse health effects when sufficiently perturbed. Such a system would evaluate biologically significant alterations without relying on studies of whole animals." See also "Toxicity Testing in the 21st Century: Better Results, Less Use of Animals", 25 *The Environmental Forum* 46, Mar/Apr 2008.

⁷⁸ See Elliott & Elliott (2009, p. 74).

that REACH proponents in Europe believe that requiring the data to be generated is good in and of itself (especially in terms of increasing awareness in industry), whether or not government considers it for purposes of regulating.

If it were correct that current and emerging science allows us to predict in advance with a higher degree of confidence than in the past which chemical substances are likely to be ‘bad actors’, and to focus greater regulatory scrutiny on those, then the extensive efforts to test all substances, even those that are highly unlikely to prove hazardous, could be seen as costly ‘dead-weight losses’ unnecessary expenses that do not contribute to protecting health and safety. In Europe, views are mixed. Defenders of REACH assert that compiling and submitting comprehensive test data on the safety of substances promotes public confidence,⁷⁹ even if government resources are insufficient to actually review all the dossiers that have been submitted.

Spill-over effects not only multiply the benefits of harmonisation; they also multiply the costs of agreeing to an inefficient duplicative system. Thus, for industry on both sides of the Atlantic, the calculus was not merely whether the benefits of harmonisation in TTIP were greater than the extra costs of trading up, as envisioned by Vogel, but whether the benefits exceed costs when both positive and negative spill-overs from TTIP to anticipated future regulatory systems around the world are taken into account.

9. What really matters: SHEC equivalence and market access

The stated rationale for giving up on the possibilities of incremental harmonisation or regulatory convergence before the negotiations even began, boils down to the idea that REACH and TSCA are “very different” (in the words of the industry joint position paper) or “too different with regard to some fundamental principles” (in the words of the EU negotiation position).

But that observation, while true, avoids or by-passes the relevant question. Negotiations over a free trade agreement always begin from the starting point that regulatory systems on the two sides are different. The proper question is whether the differences in regulatory processes

⁷⁹ The mid-term review of REACH (CSES, 2012) finds practically no empirical support for this greater confidence. Pelkmans, Schrefler & Gubbels (2013) reach the same conclusion.

are so ‘fundamental’ that they cannot reasonably be bridged. It seems never to have occurred to the TTIP negotiators that, even though processes and ‘fundamental principles’ of regulation may differ, the actual *outcomes* of these divergent processes are substantially similar in some areas, or at the very least ‘adequate’ to protect the public, in cases when substances ARE regulated by both sides. The main difference between the US and Europe seems to be that Europe often regulates on a precautionary basis but the US holds off for more definitive science that will stand up in court if challenged.⁸⁰

Empirical studies of the actual results of chemical regulation in the US and the EU suggest that despite assertions about ideological and rhetorical differences, such as the precautionary principle versus risk assessment as philosophies for regulating chemicals, the actual results of regulation in some area are not very different between the US and EU,⁸¹ at least for many substances that are regulated in both. Merely as an illustration of this similarity, we compared the chronic oral and drinking water limits for the top 30 chemicals by volume released to the environment in EPA’s Toxic Release Inventory. Table 13.1 below shows that for those substances for which both the EU and US had exposure limits, 75% (12 of 16) differed by less than a factor of 3. Only one (xylenes) differed by more than a single order of magnitude (10x). From a toxicological standpoint, differences this small at low levels such as those involved here are insignificant.

In every case, differences in the actual stringency of regulation were inconsequential, despite the fundamental differences in the processes, systems and philosophies that had been used to reach the results. It is important to note, however, that only about half of the substances (16 of 30) were regulated by both sides; in some instances the US regulated but the EU did not, but in more cases in this small sample, the EU regulated but the US did not. Of course, we are reluctant to draw any broad general conclusions from this small sample. What is important for our purposes is that there were *some* areas of overlap where duplication could be eliminated.

⁸⁰ For criticism and suggestions for improvement of the current European approach to the use of science in risk regulation, see Schrefler & Pelkmans (2014). See also Charnley & Elliott (2002), who argue that broader availability of judicial review by private parties challenging government regulation makes regulating based on suggestive but not yet definitive science more difficult in the US.

⁸¹ See Renn & Elliott (2011).

Table 13.1 Exposure limits of chemicals: US-EU regulatory comparison

Substance ^a	Difference < 3x		
	US	EU	value
Zinc	3E-1	SE-1	CR ^b
Arsenic	0.01	0.01	DW ^c
Lead	0.015	0.01	DW
Copper	1.3	2	DW
Nitrate	10 (as N)	50 (as NO ₃)	DW
Barium	2	0.7	DW
Toluene	8E-2	2.23E-1	CR
Toluene	1	0.7	DW
Chromium VI	3.E-3	5E-3	CR
Total chomium	0.1	0.05	DW
Nickel	2E-2	5E-2	CR
Chlorine	4	5	DW
	Difference > 3x		
Substance	US	EU	value
Arsenic	3E-4	1E-3	CR
Barium	2E-1	2E-2	CR
Styrene	0.1	0.02	DW
Xylenes	10	0.5	DW

- Listed in order of total volume released to the environment in the US reported in EPA's Toxic Release Inventory (highest to lowest) for which comparisons were possible because regulated in both the US and the EU.
- CR = chronic oral exposure limit in mg/kg-day.
- DW = drinking water limit in mg/L.

Source: Authors' own compilation.

It is true that drinking water is not typically shipped across the Atlantic, but what these examples suggest is that despite differences in legal procedures, when the two sides regulate a chemical, sometimes they regulate it with similar stringency. On reflection, these conclusions are not surprising. The science is the same on both sides of the Atlantic, and regulators in the US and the EU are both trying conscientiously to protect public health and the environment with an adequate margin of safety to the best of their ability and judgment. It is not surprising that sometimes they would reach similar outcomes.

Admittedly, this is not the whole story, as some substances may be regulated in the EU but not the US or vice versa. European opposition to TSCA centres around the perception that many risky substances are not tackled in the US (but this does require a much broader inspection than TSCA alone; see Box 13.1). As noted, a precise and verifiable survey of these divergences seems not to be available and is much needed. But where both sides have ‘tackled’ a high-volume substance, regulatory limits in this small sample turn out to be remarkably similar. This suggests that the TTIP negotiators were wise to focus on expanding technical and scientific assessments, which have tended to come out very close to one another in the past.

The relevant case for trade negotiations, however, is whether, when one side has regulated something, the other partner should have enough confidence that it is willing to accept those results *without* duplicating its own regulatory processes. The absence of significant differences in this example where both sides have addressed high-volume substances, should give confidence that in at least some instances, as former Ambassador Eizenstat (2103) put it, “we should have confidence in the 21st century that the regulatory standards in both the EU and US are adequate to protect our publics and should be accepted ...”

International negotiations often begin this way with each side insisting that its system is best. The more productive question is whether the other side’s system is good enough, given one’s SHEC objectives.⁸² For trade negotiations such as TTIP to succeed, both sides must move beyond familiar national legal *procedures* for regulating chemicals, to ask whether the actual *results* are comparable and acceptable in terms of protecting against risky chemicals, despite differences in the legal procedures that lead up to them. Ultimately, this is about the SHEC objectives, the societal benefits the citizens and workers care about. Comparability includes, however, both what substances need to be regulated and how stringently they are regulated once regulation is put in place.

⁸² See Executive Order 13609, Promoting International Regulatory Cooperation, 1 May 2012, §1 www.gpo.gov/fdsys/pkg/DCPD-201200327/pdf/DCPD-201200327.pdf: “[i]n meeting shared challenges involving health, safety, ... environmental, and other issues, international regulatory cooperation can identify approaches that are *at least as protective as those that are or would be adopted in the absence of such cooperation.*”

Perhaps the particular high-volume chemicals in water in Table 13.1 are an exception. We really don't know objectively how much convergence in outcomes actually exists despite differences in regulatory processes. But even if areas of similar regulatory outcomes are 'islands of convergence in a vast sea of difference', they show that in some areas greater harmonisation for mutual benefit should be possible. Plus the size of the islands of convergence would be expected to grow over time as TSCA reform is implemented and greater collaboration occurs between the US and the EU at the scientific and technical level.

The challenge for a 'living' TTIP is to create a process that will i) gradually identify other islands in which regulatory outcomes are similar, or at least, 'good enough' to protect the public, and ii) provide a mechanism to eliminate needless duplication and inconsistency in those islands, however large or narrow they may be.

10. A proposal: Unilateral recognition under TTIP

To date, those seeking convergence of regulatory systems have tended to focus on 'mutual recognition', the idea that each side will accept the other's regulation as adequate.⁸³ This approach is particularly problematic when one side has regulated a substance but the other has not. Would the European side be required to accept a US EPA decision *not* to regulate because risks were assessed to be very low? That is not likely to happen, at least not any time soon, as many Europeans apparently still perceive Americans as swimming 'in a toxic soup of poisonous chemicals' (as Europe itself presumably also must have been before REACH was enacted in 2006). It remains surprising why so few Europeans seem to wonder why US citizens would accept that, not to speak of workers, but we refer to the discussion in section 4.

There are, however, other approaches to achieving greater regulatory convergence that may be more promising, particularly

⁸³ For a classic statement of the case for mutual recognition, see Eizenstat, *supra* note 42. For the many forms of mutual recognition, including MRAs, see Jacques Pelkmans & Anabela Correia de Brito, *Study on Mutual Recognition Agreements*, OECD, Paris, forthcoming (2015). A survey of how mutual recognition works in the goods and services markets in the EU is found in Jacques Pelkmans (2012), "Mutual recognition: economic and regulatory logic in goods and services", in T. Eger and H-B. Schaefer (eds), *Research Handbook on the economics of EU law*, Cheltenham: E. Elgar.

when one side or the other is particularly 'dug in' about the superiority of its system, as some groups and some governments in Europe appear to be about REACH, and the US appears to be about risk-based regulation.

An option that one of us has proposed is called 'optional asymmetric recognition'⁸⁴ Under such a system, a regulated party would be given the option to opt-into the regulatory system for a chemical that is perceived by the TTIP negotiating parties as more stringent, such as REACH. Thereby, the costs of duplicative regulatory processes in the second country could be avoided in at least some instances in which "the game was not worth the candle". It is even possible to trade asymmetric recognition in one area, where one side is perceived as more stringent, for asymmetric recognition in another area, where the other sides' regulations are perceived as more stringent. (This is actually the usual situation in negotiations, in which it is rare to trade like for like; rather, the path to a successful negotiation generally involves trading away something that one values less but the other sides values more.)

If a company decided that the potential 'over-regulation' under REACH was not worth arguing about, the company could decide to have the REACH restrictions become legally binding in the US, and thereby avoid the costs of going through a duplicative regulatory process in the US. These conditions are most likely to be satisfied when (1) the costs of going through duplicative regulation are relatively high, but (2) the marginal costs of accepting over-regulation are relatively low, such as because the company expects to sell the same product everywhere anyway. For example, assume that a pesticide is already registered in the EU, and the producer intends to sell exactly the same formulation in the US. If we know that EU regulation is more stringent, what is the value in requiring the company to re-register the product in the US? The same would be true for anti-microbials, or additives for cosmetics. Companies should have the option of accepting a more stringent regulatory result as the *de facto* international standard. In this way, a *de facto* harmonised standard may develop internationally from the bottom up, rather than top down, as many countries gradually defer to a single regulation as adequate to protect their publics. In practice, many companies selling products internationally already, adopt a

⁸⁴ The discussion of "optional asymmetric recognition" is based on a presentation by Donald Elliott to the European Risk Forum in Brussels, 11 June 2013.

single design standard for their products worldwide rather than making different products for different markets depending on vagaries of local regulations.

But optional asymmetric recognition would not work in the other direction: EPA's failure to regulate something, or having less stringent regulation than under REACH, would have no legal consequences. Thus, optional *asymmetric* (or, unilateral) recognition differs from *mutual* recognition in that it is a one-way street, and that it is optional, not automatic. But optional asymmetric recognition has the advantage that some of the gains from eliminating duplicative regulatory burdens can be achieved in a situation where only one side trusts the other to regulate adequately albeit perhaps too stringently. Thus, if the US side believes that EU regulation under REACH may be too stringent in some instances, but the EU believes that US regulation is not stringent enough in some instances, mutual recognition is a non-starter. Yet, there still may be some situations in which some gains are still possible through asymmetric (*i.e.* unilateral) recognition of the other side's regulation as adequate and these potential gains should not be left on the table in TTIP negotiations. Gains from optional asymmetric recognition would generally occur when the costs of duplicative regulation are greater than the excess costs of what is perceived to be 'more stringent than necessary' regulation. It may seem intuitive that there would be few such situations, but that is not necessarily the case if companies are manufacturing and selling into multi-national markets, as they often are for chemicals. If a company is selling in both the US and the EU, and is already regulated in the EU, requiring the company to go through a duplicative regulatory process in the US when it would be willing to carry over EU regulation into the US, is a pure and costly deadweight loss. Moreover, to maintain public confidence, the most stringent standard by a major trading partner may well become the *de facto* regulatory standard worldwide. Why not negotiate an agreement that US companies may opt in to REACH regulation in the US when they do not object to doing so?

11. Conclusions

As Otto von Bismarck famously stated in the remark that we quote in the epigraph at the beginning of this chapter, "Politics is the art of the possible." From that standpoint, the TTIP negotiators were probably wise to focus on the modest but important goals of eliminating tariffs, sharing datasets, standardising labelling and expanding sharing the technical work of assessing priority chemicals at the scientific level.

While proponents of harmonisation of regulatory systems, such as Ambassador Stuart Eizenstat, admonish us that “we *should* have confidence in the 21st century that the regulatory standards in both the EU and US are adequate to protect our publics and should be accepted”,⁸⁵ regrettably, that mutual confidence that he asserts “should” be taken for granted, does not yet exist. The difference between the EU and the US over whether regulation should be precautionary, or based on more mature, demonstrated science continues to be a fundamental divide at this time. Perhaps greater confidence will come later in the 21st century after a period of working together at the technical and scientific level.

One critical focus we strongly advocate is to establish authoritatively in what areas the level of SHEC protection for substances which are regulated on both sides is similar. Establishing this is, as we have shown, a major task in and by itself. In areas where that similarity is found, it would open possibilities for much greater ambition in TTIP for chemicals. Unfortunately, but also surprisingly, the knowledge about the areas and substances which are regulated in some form (be it by precisely identified regulation by agencies or in annexes of a range of laws, or otherwise, including judicial review and the chilling effect of liability suits) is rather imperfect, in particular in the US. Knowing the possibilities for liability cases in the US and realising that chemical substances are regulated outside TSCA (under other laws and statutes, and by federal agencies) far more often than under TSCA, the European perception that protection against risky chemicals in the US is often lousy or even absent, is almost certainly profoundly mistaken. We recommend that TTIP should include a trans-Atlantic body that is assigned with assessing objectively the actual outcomes (i.e. levels of protection against risky chemicals) of divergent regulatory processes and identifying those areas where differences in the level of protection are not material, that means, equivalent. These findings should lay the foundation for greater but well-targeted ambition in lowering the costs of TBTs, so high in transatlantic chemicals trade. Getting US and EU negotiators (and the governments behind them) out of their trenches may well hold significant promises for economic gains, without affecting in any way the achieved protection against risky chemicals.

⁸⁵ Stuart E. Eizenstat, A new transatlantic partnership (April 2013) (italics supplied), <http://esharp.eu/essay/23-a-new-transatlantic-partnership/>, quoted *supra* page 26.

However, apart from this very long run perspective, we also discuss at some length the EU suggestions done in November 2014 and some of the background issues behind those. We regard them as modest, given what TTIP stands for from its start, but useful. However, chemicals trade suffering from the second-highest TBTs over the North Atlantic, the EU suggestions are expected to do little in reducing TBT costs in the short to medium run. Nevertheless, the EU suggestions, modest as they are, might have become more problematic because of the somewhat defensive EP TTIP resolution of 8 July 2015 although the authors are not convinced that this is necessarily the case. Seen in this political climate, what might be regarded (e.g. by the authors) as a modest proposal for chemicals in TTIP – never mind, the US position on chemicals about which little is known – may well be the maximum possible for a while to come. This is regrettable but a political fact of life. It renders the main message in our chapter even more crucial: in the final analysis, what really matters is where the US and the US do protect citizens and workers against risky chemicals and, if both do this in an equivalent manner, how can trading costs be sliced without ever touching SHEC objectives? Finally, we suggest an easy and relatively simple solution to facilitate market access and reduce the costs of duplication for companies selling in both the EU and US markets, in case the substance is regulated on both sides. Called (asymmetric) unilateral recognition, it would allow a company to opt-in into the most stringent of the two regulatory regimes for substance *z*, thereby having to comply only once, and get automatic recognition, hence market access, in the less stringently regulated market (for this substance). For those substances, costs could be cut considerably. Many chemical companies including SMEs do indeed sell in both Europe and the US and would benefit directly without setting up TTIP harmonisation. By definition, it would imply a race-to-the-top for these substances.

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