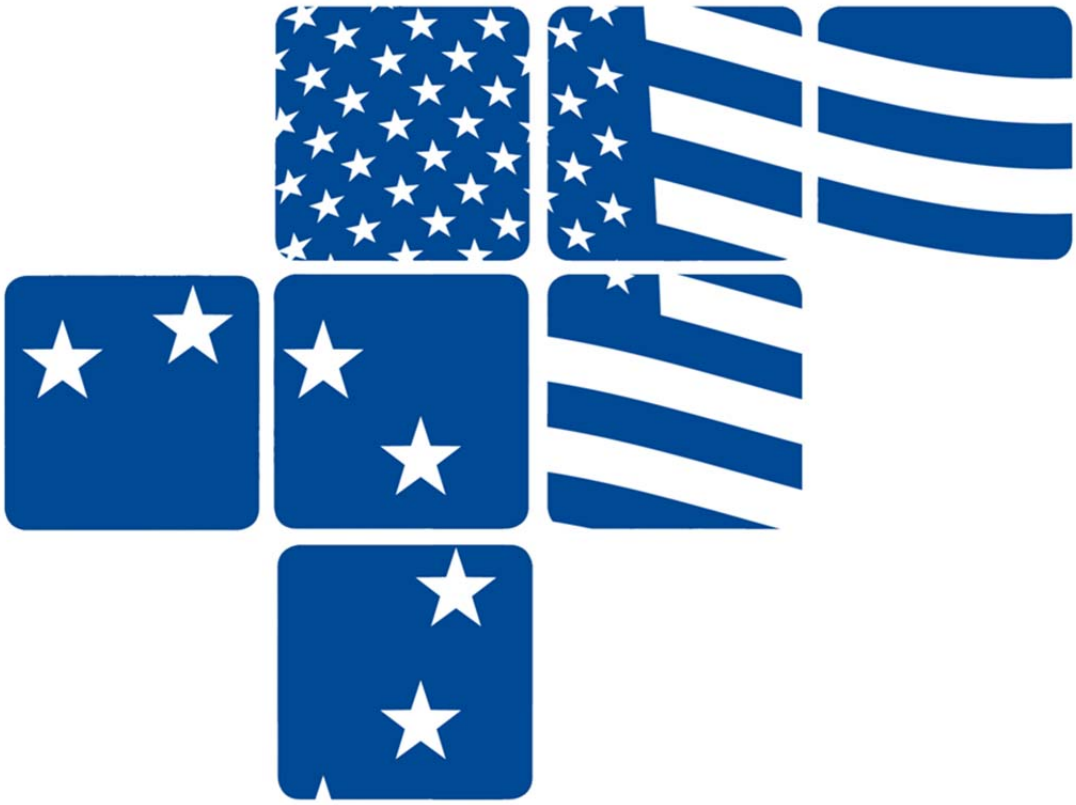
Regulatory Co-operation and Technical Barriers to Trade within Transatlantic Trade and Investment Partnership (TTIP)



Kommerskollegium
National Board of Trade

Preface

A central question in the current trade negotiations between the U.S. and the EU is that of the regulations and requirements that exist for various products to ensure that they will be safe to use or to protect the environment or human health. The U.S. and the EU have about the same levels of protection, but their regulatory systems have been designed in completely different ways which result in that some regulations create unnecessary barriers to trade between the U.S and the EU. Since both regulatory systems have developed over a long period and are well established, regulatory coherence aspects related to legitimate obejctives, such as health and safety, will become one of the more difficult issues to agree on.

At the same time, TTIP offers a special opportunity to reduce the differences in regulations that form a disruptive barrier to world trade. The size and influence of the U.S and the EU mean that reached agreements can influence the regulations of other countries, and thereby reducing the negative effect that differences in regulatory frameworks have on international trade.

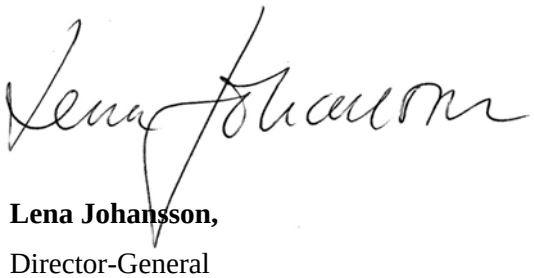
In the present report, we analyse the differences in regulations for a number of sectors in more detail. We may conclude that the differences are quite varied in nature and should therefore be tackled in multiple ways. We also see that differences in society's horizontal regulations affect various sectors in different ways.

The work was led by Heidi Lund, who prepared the report together with Emanuel Badehi Kullander, Anna Folkesson, Cedric Housset, Åsa Pleiner and Beatrice Tander Gellerbrant. We are grateful for the assistance received from a number of Swedish stakeholders.

It is our hope that the analysis will be of use in the negotiations. We also hope that our work may contribute to greater insight about the significance of regulatory issues in a modern economy, where production is divided in supply chains, where parts of the production are taking place at different locations, often in different countries. Production is thus becoming more and more dependent on trade functioning smoothly.

Last, but not least, we hope that our work might increase understanding of what the differences between the EU and the U.S. mean in practice. As mentioned above, the requirement levels are similar. The differences lie in the method of regulation.

Stockholm, March 2014



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Contents

1. Introduction

The Swedish National Board of Trade (hereinafter also “the Board”) has made an analysis of regulatory cooperation and potential solutions for technical barriers to trade between the EU and the U.S.

The analysis presents the regulatory systems for goods in the EU and the U.S. and reviews the relationship of the forthcoming free trade agreement to the WTO legal framework. The sector analysis is based on the pre-selected sectors of automotives, information and communications technology (hereafter ICT), chemicals, pharmaceuticals and medical devices, and illuminates Swedish interests and to what extent they coincide with views expressed by various stakeholders within the European Union.

The overarching issues treated in the analysis are:

- The relationship between TTIP stipulations and already concluded multilateral arrangements (WTO/TBT, other FTAs) and any conflict with the use of existing structures, e.g. systems of technical harmonisation in the markets, standardisation structures, authority structures and enforcement (market surveillance)

- Areas within sectors assumed to be an appropriate start and able to yield good and quick results for increased regulatory coherence

- Areas that are particularly well suited to mutual recognition and harmonisation or other regulatory tools

- Possible ways forward in terms of ongoing regulatory work, a possible mechanism for the development of future regulation and a position on how TTIP could take the non-harmonised regulatory framework into consideration

- Balance between enhanced market integration while retaining the legitimate interests of e.g. health and safety

- Views on how TTIP can take into account the parties' conceptual differences in the issuing of regulations

The analysis does not have the ambition of providing precise negotiation priorities. The idea is instead to have a system-wide perspective with regard to the regulatory approaches at hand and to increase knowledge about key problems. The analysis has generated a comprehensive problem description that illustrates the complexity of the regulatory issues surrounding TTIP. The fact that there is very little documentation available indicating the specific intentions of the EU and the U.S. naturally made the analysis more difficult. For example, it is unclear how far the EU and the U.S. are willing to go in order to reach regulatory coherence bilateraly and regarding the premises of FTAs and the multilateral trading system. An important starting point here is that TTIP should not result in deteriorated trading

conditions for third countries. Rather, TTIP should result in improved conditions for global trade in general.

Many of the background papers and initial regulatory dialogues drafted out a somewhat naive desire to solve the entire transatlantic regulatory landscape by using one regulatory model. More specifically, there have been ideas about trying to resolve technical barriers to trade between the EU and the U.S. through a horizontal system of technical harmonisation similar to that applied in the EU. The analysis now performed makes it however possible to conclude that the key is to to find solutions for specific areas of mutual interest. Further, what was initially presented as impossible, such as the compatability of regulatory agencies and structures for standardization in the EU and the U.S., does not appear quite so difficult; that is, if the EU and the U.S. can agree on joint processes when developing more compatible and coherent regulations in various areas.

1.1 Method and limitations

The analysis was carried out in the form of a literature study and through in-depth interviews and discussions with representatives from government agencies and industry.[1] As the National Board of Trade investigates patterns and trends in transatlantic trade on a regular basis, also earlier work serves as a foundation for this analysis. Particularly with regard to the analysis of sectors, feedback from Swedish regulatory agencies and companies was decisive for the outcome. Here it can be noted that the contributions varied greatly, as a consequence, the sector studies cannot be considered completely comparable.

The analysis of regulatory issues and technical barriers to trade encompasses several major issues – both with respect to the horizontal systems for product regulation in the EU and the U.S., and to sectoral conditions for increased regulatory transparency and regulatory approximation. This has led to a need to impose some clear limitations on the analysis.

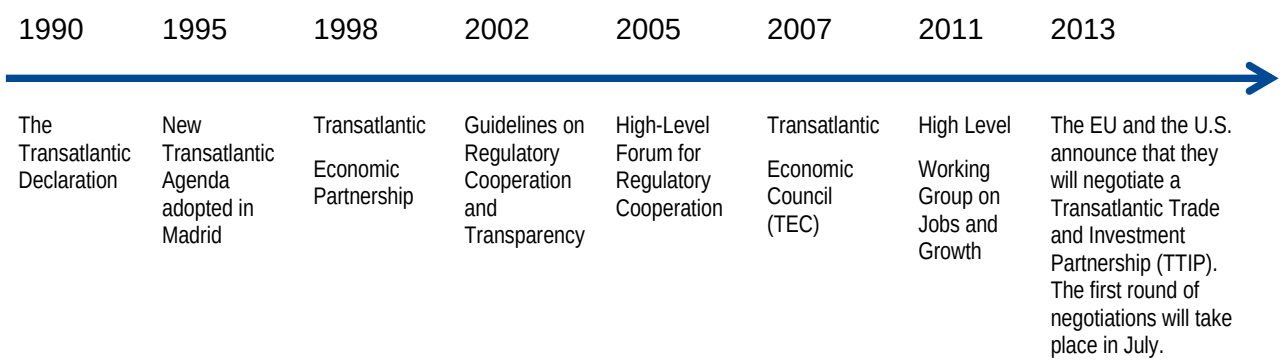
The study limits itself to goods only and technical aspects in particular, while most of the areas also that are subject to analysis in this study also concern services (e-accessibility, ICT and mobile networks). Most of the sectors are also affected by regulations which are more horizontal in nature and not only product specific in other policy areas, such as public procurement, data protection (medical devices) or the environment (automotives), that is, areas that are treated outside the WTO Agreement on Technical Barriers to Trade. However, it has not been feasible for this assignment to include more detailed analysis of these

[1] On 11 December 2013, the National Board of Trade together with Teknikföretagen held a public hearing on the regulatory aspects of TTIP. Around fifty Swedish stakeholders attended: the Swedish Work Environment Authority, the National Board of Housing, Building and Planning, the Ministry for Foreign Affairs, the Swedish Post and Telecom Authority (PTS), the Swedish Transport Agency, the Medical Products Agency, the Swedish Board for Accreditation and Conformity Assessment (Swedac), the Royal Institute of Technology (KTH), Business Sweden, Teknikföretagen, LIF - the research-based pharmaceutical industry in Sweden, the Swedish Standards Institute (SIS), the Swedish Textile and Clothing Industries Association (TEKO), Svensk Elstandard (SEK), ITS, BILSweden, Kollmorgen AB, Electrolux Appliances AB, the Swedish Association of Vehicle Importers (BIRF), Von Lode Advokat AB, Electrolux, DeLaval International AB, Ericsson, H&M, Intertek, NorStella, Scania, Kleen Consulting. In addition, interviews and meetings were arranged in November and December 2013 with the Swedish Chemicals Agency, the Medical Products Agency, the Swedish Post and Telecom Authority (PTS) and the Swedish Transport Agency, the Embassy of Sweden in Washington, AkzoNobel, BIRF, BILSweden, IKEM - Innovation and Chemical Industries in Sweden, Scania, AB Volvo, Ericsson, Sony Mobile Communications AB, Intertek, Swedish Medtech, Swedish Standards Institute (SIS), CEN-CENELEC and Von Lode Advokat AB.

additional aspects. It is only possible to note that in the analysis of product regulations and in the process of choosing negotiating positions, it is desirable for both the EU and the U.S. to look beyond individual product sectors, and where possible, also consider other areas in order to achieve an overall view of priorities. This is especially important in areas where the EU's current regulatory model contributes to the international competitiveness of business.

An important part of the analysis is taking stand on possible Swedish priorities. The analysis shows that there are differences in priorities and preferences regarding TTIP, not only between government agencies and businesses, but also within a sector. This is linked, for example, to company size and the investments a company has made with respect to adaptation to the regulations at U.S. market. From the point of view of regulatory authorities, major changes in existing regulatory frameworks would naturally require readjustment. At the same time it may be noted that international regulatory co-operation exist already in a number of sectors analysed within the scope of this study.

2. Transatlantic cooperation – a historical résumé



Over the past 20 years, a series of initiatives have been developed to enhance transatlantic regulatory cooperation. These initiatives have led to an increased understanding of the parties' regulatory systems. To further develop transatlantic cooperation, the leaders of the EU and the U.S., as part of the Transatlantic Economic Council (TEC), decided to establish a High Level Working Group on Jobs and Growth. The Working Group was tasked with identifying reforms and commitments that could boost trade and investment between the two parties, to promote employment, growth and enhanced international competitiveness. In its final report, dated 11 February 2013, the Working Group presented its proposal for a comprehensive agreement addressing bilateral trade and investment issues, including regulatory issues. It also stated that the agreement as such should contribute to the development of globalregulations.[2]

On 13 February 2013, the leaders of the U.S. and the EU announced that the parties intended to initiate their respective internal procedures to be able to commence free trade negotiations. On 14 June 2013, a mandate for the European Commission to negotiate a Transatlantic Trade and Investment Partnership (TTIP) was adopted through a decision of the Foreign Affairs Council. The first round of negotiations between the EU and the U.S. took place in July 2013.

In its final report, the High Level Working Group recommends, inter alia, the EU and the U.S. to negotiate an ambitious “TBT-plus” chapter, an ambitious “SPS-plus” chapter, a horizontal chapter on regulatory coherence and transparency for the development and implementation of efficient and more compatible legislation for goods and services, special provisions or annexes for selected sectors as well as a framework for identifying opportunities for future regulatory cooperation, including provisions that provide an institutional basis for future progress.

[2] Final Report High Level Working Group on Jobs and Growth, 11 February 2013, http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc_150519.pdf.

2.1 Sectors

In the autumn of 2012, the EU and the U.S. requested concrete proposals to address the regulatory differences between the EU and the U.S. The Commission and the *Office of the United States Trade Representative* (USTR) received statements from a range of stakeholders in different sectors, both joint EU-US statements and those from either side of the Atlantic. *These joint statements from the sectors serve as a basis for EU and U.S. work to identify transatlantic sectoral interests for the TTIP negotiations.*

At the press conference in December 2013, in conjunction with the third round of negotiations, it was still not clear how TTIP should address the sectors identified by the parties as particularly important for regulatory cooperation (automotives, pharmaceuticals, chemicals, textiles, medical devices, ICT and cosmetics).[3] The same event revealed that the sectors currently identified do not constitute a final selection, but more sectors might be added in the course of the negotiations.

2.2 The indicated position of the U.S.

A clear indication of what the U.S. communicated ahead of the TTIP negotiations concerning regulatory issues may be inferred from a speech made by the U.S. Trade Representative in September 2013.[4] The U.S. focused on:

- Transparency
- Participation
- Accountability

In the same speech, the U.S. Trade Representative criticised the EU for not being sufficiently transparent in the legislative process and the EU system of standardisation for being closed.

2.3 Swedish TTIP negotiating positions and national hearing

On 11 December 2013, the National Board of Trade, the Ministry for Foreign Affairs and Teknikföretagen invited representatives from Swedish regulatory agencies and industry to a hearing. The aim was to identify existing barriers in U.S. trade and gather Swedish positions in order to achieve the best outcome of ongoing negotiations.[5]

Based on the views that emerged during the hearing the following conclusions may be drawn:

[3] Press conference with EU representative Ignacio Garcia Bercero and U.S. representative Daniel Mullaney on 20 December 2013.
[4] U.S. Trade Representative Michael Froman delivered a speech at the German Marshall Fund in Brussels on 30 September 2013, http://www.ustr.gov/about-us/press-office/speeches/transcripts/2013/september/froman-us-eu-ttip.
[5] About 50 actors attended the hearing, as listed in footnote 1.

Aggregated level
Trade can be simplified through increased transparency and an increased information-supply with regard to the applicable requirements in each sector, down to the product level if possible. In many cases, it may be presumed to be difficult to amend the parties' current legislation. As a consequence, a greater consensus should be advocated on the design of future regulatory frameworks. With regard to future regulation, there is great potential in laying, already now, a common regulatory foundation in certain sectors, such as for the environment, conflict minerals and nanomaterials.[6]

Sector-specific level
Individual sectors should be studied carefully in order to reach consensus on how specific problems may be resolved. There is a large intermediate layer of regulations, which can be difficult to manage at present. These concerns, for example, limit values and standards, which the EU and the U.S. should try to revise jointly in the future.

Other specific regulatory issues raised at the hearing were:

- Mutual recognition of procedures for conformity assessment: Participants from various sectors considered mutual acceptance of testing and certification to be an overarching regulatory issue that should be resolved during the negotiations.

- Third-party certification vs. self-declaration: A clear opinion shared by hearing participants was the importance of safeguarding EU interests by not introducing third-party inspection in the EU.

- Marking and labelling: Participants advocated measures to make progress towards more uniform marking and labelling rules.

- The level of TTIP application in the U.S.: Participants considered it very important for TTIP to encompass the state level, i.e. that TTIP should not be limited to the federal level.

- Varying needs of different industries: Participants pointed out that different industries have different needs. In some industries, standards, for example, pose no problem, whereas they do pose great problems in other industries.

- Other barriers to trade (Non-Tariff Barriers/NTB): Participants also pointed at other barriers besides technical barriers to trade as being relevant to TTIP, e.g. public procurement.

- Other policy areas: Participants felt that it was important to have a system perspective, that is, to consider horizontal legislation havingan impact on the various sectors, such as environmental legislation.

[6] Industry also stressed that, from a global perspective, the EU's current regulatory model can be regarded as a competitive factor.

3. TTIP in the multilateral trading system

3.1 General conditions for WTO members to conclude free trade agreements

This section of the study describes how TTIP relates to the multilateral trading system and consists largely of three parts. Firstly, how TTIP relates to the WTO legal framework and the conditions for WTO members to conclude free trade agreements. Secondly, how potential TBT sections in TTIP relate to the WTO Agreement on Technical Barriers to Trade (the TBT Agreement). Thirdly, how TTIP affects already concluded free trade agreements with third countries.

3.1.1 The legal framework according to the GATT

The conditions for WTO members to conclude free trade agreements (FTAs) are governed by GATT Article XXIV. This provision states that it is, in principle, permissible for WTO members to form free-trade areas. Article XXIV:4 states that the purpose of a free-trade area should be to facilitate trade between the constituent territories and not to raise barriers to the trade of other contracting parties with such territories. FTAs can therefore in principle be considered permissible in so far as they do not impede trade within the WTO system.

However, the opportunity to conclude FTAs is not without conditions. Article XXIV:5 contains certain conditions that must be met for a free-trade area (free trade agreement) to be established, namely: that the duties and regulations of commerce imposed are not more burdensome than those that existed in *each constituent territory individually* in relation to third countries, and, where an interim agreement is adopted, that a plan and schedule for the formation of the free-trade area shall be drawn up within a reasonable length of time. Article XXIV:6 stipulates that where a contracting party under the free-trade area proposes an increase in the rates of duty, negotiations must be initiated with other WTO members according to the procedure in Article XXVIII.

The WTO's dispute settlement mechanism has on numerous occasions examined whether various FTAs[7] can be reconciled with the above-mentioned requirements of GATT Article XXIV, and how the assessment of an FTA's impact on the multilateral trading system should be made. In the dispute *Turkey – Textiles*, in which India complained that Turkey's rapprochement with the European Union (at the time of the dispute European Community) implied that Turkey was deviating from the Agreement on Textiles and Clothing and GATT Article XI, the Appellate Body pronounced that members should to the greatest possible extent avoid creating adverse effects on the trade of other Members.[8] Furthermore, the Appellate Body stated that Article XXIV may permit certain deviations from GATT provisions if the customs unions[9], in addition to the fulfilment of the conditions of GATT

[7] Note that the WTO uses the term RTA. RTA encompasses customs unions, free trade agreements, investment agreements and integration agreements. Henceforth, the term FTA is used for free trade agreements, which TTIP will probably be defined as.
[8] Appellate Body Report, *Turkey – Textiles, p. 57.*
[9] Note that the dispute concerned a customs union (see GATT Article XXIV:8 (a) (i)) and thus not an FTA of the kind now being negotiated between the EU and the U.S.

Article XXIV:5 (in this case, the requirements applicable to customs unions), could not be established if the parties were prevented from introducing the disputed rules.[10]

In summary, it is possible under certain circumstances to deviate from WTO regulations on the formation of FTAs. It should however be noted that the possibility to deviate is connected to a relatively onerous burden of proof for the party defending the measure – since the state in question firstly must prove that the effect on trade is severely restricted, and secondly, demonstrate the provision's necessity for the very possibility of implementing the FTA.

3.1.2 The transparency mechanism for FTAs

Since 2006, there has been a transparency mechanism for FTAs.[11] In short, the transparency mechanism implies that members that are planning to conclude FTAs are to notify their intentions to the WTO and to provide information on the proposed agreement. The transparency mechanism should be viewed in light of the above-mentioned provisions of GATT Article XXIV and especially the difficulties of adequately specifying the proposed agreement's consequences in a way that goes beyond the tariff aspects. The effect on the trade of other members is more difficult to establish for *other regulations of commerce* as compared with only *duties,* which are more static in form. In other words, the transparency mechanism aims to facilitate the foreseeability of FTAs impact on the multilateral trading system and to involve other members in the evaluation process.

The transparency mechanism largely contains the following parts: early announcement of the FTA, notification of the FTA, procedures to enhance transparency, notification of changes and a report on how the final agreement fulfils the parties' liberalisation commitments. It is notable that the mechanism mandates the WTO Secretariat to prepare a report on the agreement that can then be commented on by the other members.[12] FTAs are notified to the Council for Trade in Goods (CTG), which forwards the matter to the Committee on Regional Trade Agreements ("CRTA") for investigation.[13]

3.1.3 Jurisdiction and dispute settlement

In order for TTIP to function properly, issues concerning infringement and dispute settlement will have to be regulated under the agreement. Several questions can be raised in this regard; which body/court will, for example, be competent to examine a situation where potential irregularities arise between the parties, how does that examination relate to the regime enshrined in the multilateral trading system, the WTO *Dispute Settlement Understanding* (DSU) and how are purely procedural aspects to be handled, such as *lis alibi pendens*[14] and *res judicata*[15]?

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[10] Ibid. 58-59.

[11] See the procedure according to the decision concerning notification of FTAs on the WTO Secretariat website: http://www.wto.org/english/tratop_e/region_e/trans_mecha_e.htm.

[12] Since 1995, no report has been able to be concluded due to lack of consensus.

[13] This procedure applies when the FTA falls under GATT Article XXIV. Agreements that fall under the Enabling Clause (agreements between developing countries) are considered by the Committee on Trade and Development ("CTD"). FTAs concerning services are considered by the Council for Trade in Services (CTS).

[14] Means that a dispute may not be tested in parallel to a pending legal process concerning the same dispute (regarding matter and parties).

[15] Means that the same dispute may not be tested again after a final judgment has fallen.

The 1969 Vienna Convention establishes a basic order of international law on how treaties are to relate to each other. The Vienna Convention is thus a good starting point for clarifying how TTIP will relate to the WTO. According to Article 30 on the *Application of successive treaties relating to the same subject matter*, in the case of two simultaneously applicable treaties, the earlier treaty applies only to the extent that its provisions are compatible with those of the later treaty (paragraph 3). Consequently, a later treaty, in this case TTIP, would according to the current wording take precedence over the earlier treaty, that is, the WTO Agreement.

The WTO's dispute settlement mechanism, DSU, contains wording that specifies the relationship between WTO dispute settlement and international law. Article 3.2 states that the WTO's dispute settlement system serves to clarify the provisions of these agreements in accordance with customary rules of interpretation of public international law. Thus, the interpretation of the WTO Agreement shall, in principle, follow the Vienna Convention's rules of interpretation. Furthermore, Article 23 states that when members seek redress for violations under the covered agreements, they shall abide by the rules and procedures for dispute settlement under the DSU. It thus appears that there is a relationship between, on the one hand, international law and, on the other hand, WTO regulations, whereby the WTO has exclusive competence to rule on issues solely covered by WTO regulations. If, however, the issue is covered both by WTO regulations and an FTA, it is much less clear which regulatory regime should prevail – the DSU or dispute settlement provisions in the FTA? At this point, there appears to be a lack of conformity between the two systems.

According to what has been described above, the matter – that which is to be examined by the court – has a decisive bearing on which regulations, the WTO or the FTA, that should take precedence. From a more practical context, it seems however very difficult to determine whether the matter only concerns the WTO or the FTA. Legal issues that are subject to dispute settlement are oftenly complicated in a way that makes it difficult to exclude, in advance, the applicability of WTO provisions. For example, it is not particularly likely that a WTO panel would refuse a legal examination only because the matter, according to the FTA, is to be assessed according to its own provisions – WTO aspects are difficult, if not impossible, to distinguish from the FTA prior to an examination.[16] It is reasonable that this view would also result in the question of *lis alibi pendens* and *res judicata* becoming less important, particularly if in the case of WTO-related issues, the FTA refers to the *Dispute Settlement Body* (DSB). A WTO panel would probably not decline an examination since WTO aspects may not, in principle, be treated within the framework of an FTA (see, *a contrario*, DSU Article 23.3).

In terms of existing FTAs between the EU and third countries, there are various examples of how the dispute settlement issue has been handled. In the FTA with Chile (2003), the WTO's dispute settlement system has precedence regardless of whether it concerns the WTO or the FTA. For the FTA with Cariforum (2007), issues concerning the WTO are to be treated according to the DSU. The FTA also stipulates the possibility of using a court of arbitration for this purpose. However, a party may not raise an issue concerning the same measure until the dispute settlement process is completed in the forum first chosen by the party. The FTA with South Korea (2009) states that no party should be prevented from taking measures within the framework of the WTO. The agreement allows, however, that another court of

[16] This description should also highlight the difficulty in agreeing to waive the DSU in an FTA. See *Overlaps and Conflicts of Jurisdiction between the WTO and RTAs*, Kyung Kwak and Gabrielle Marceau, in Regional Trade Agreements and the WTO Legal System, Oxford University Press, 2006, pp. 470-471.

arbitration may be used. It should be noted that a party may not initiate a new dispute in another forum until the first dispute initiated is completed, if the matter concerns the same measure. What is common to these agreements regarding dispute settlement is that no agreement deprives any WTO member of the opportunity to initiate a dispute at the WTO.

In view of the above, it is very important that TTIP contains clear and predictable provisions for dispute settlement in order to as far as possible avoid the difficulties of interpretation that exist between WTO law and the Vienna Convention. The dispute settlement model in TTIP should promote the WTO dispute settlement mechanism to the extent that this is possible. There are several reasons for promoting the WTO dispute settlement mechanism. Firstly, the WTO's dispute settlement mechanism offers an established and recognised dispute settlement procedure that has proved to be very reliable. There is a considerable number of handled disputes and thus also a bank of "case law" that gives an idea of how a particular issue or area has been assessed by a panel, including opportunities for countermeasures.[17] Secondly, the WTO's dispute settlement system is transparent and allows third parties to observe disputes. Centralised management of disputes provides a clearer rationality of the system – disputes are registered in a database and handled in a similar way. Thirdly, a solution based on the WTO's dispute settlement system counteracts the undermining of the multilateral system and reduces the risk of bilateral agreements undermining core principles, such as transparency, predictability and non-discrimination.

Benefits of regulating dispute settlement according to a particular procedure in TTIP may be that dispute management is allowed to go faster and offers more flexibility. One possible solution, that would be able to take procedural efficiency into account, would be to include more thorough descriptions of the preliminary procedural stage, e.g. mediation and such dispute settlement processes that are available through the TBT Agreement. In this way, dispute settlement under TTIP would be more of a first instance, where the EU and the U.S. may consult their way to a solution. In the WTO, most disputes are resolved at this pre-procedural stage, and if the equivalent were to apply to TTIP, any efficiency losses of dispute settlement via the WTO would be resolved by a potentially more effective mediation.

3.2 Analysis of potential TBT sections in TTIP and their relation to the WTO's TBT Agreement

It is still difficult to fully analyse potential horizontal TBT sections in TTIP. There are as yet no consolidated agreement texts to work from. Therefore, the starting point for this analysis is to try to gain an idea of how potential TBT sections might be formed and how different solutions relate to existing multilateral solutions under the WTO's TBT Agreement.

3.2.1 Possible solutions and the TBT Agreement

A TBT section in TTIP might include provisions on transparency, standards, conformity assessment, marking, labelling and the free movement of goods. Since several of these solutions might touch upon existing provisions of the TBT Agreement, it is important that TTIP solutions are consistent with EU and U.S. obligations under the TBT Agreement.

[17] Evenett and Stern, *Systemic Implications of Transatlantic Regulatory Cooperation and Competition*, pp. 13-14.

Procedures to enhance transparency are particularly relevant since the TBT Agreement contains a relatively extensive notification procedure for technical regulations, standards and conformity assessment. The notification procedure means that WTO members must notify their draft technical regulations to the WTO Secretariat, which then makes them available to the WTO collective. A minimum two-month standstill period commences after notification.[18] This standstill period implies that all WTO members are allowed to comment and discuss the draft prior to adoption. Comments received are to be observed, and the notifying member shall explain how the draft takes the comments into consideration or how a revised draft does so. This system is well developed within the WTO sphere, and it would be troublesome, not to say questionable in terms of WTO law, if TTIP were to start out with the aim of having overlapping notification procedures which would undermine that of the TBT Agreement. It is therefore appropriate if current proposals for enhanced transparency in the TBT section in TTIP primarily start out to identify areas for improvement within existing TBT structures – notification of draft TBT measures regardless of the type of act and regulatory level, as well as commitments to respond to comments and questions on draft technical regulations. It must be stressed, however, that these commitments are already a consequence of the TBT Agreement, and thus mean nothing new in themselves. It therefore appears that it is a question of finding more extensive and bilaterally more uniform ways to interpret and apply the TBT Agreement. This would in principle be a good solution with regard to the above reasoning, that the TBT Agreement must not be undermined.

One question that must also be asked in this case is *how* to improve the implementation of the TBT Agreement between the EU and the U.S. – the TBT Agreement will have the same content both before and after TTIP and thus entail no material changes. It would therefore be appropriate if TTIP were to contain a number of improvement measures based on existing frameworks; introduction of publicly available TBT registers (probably in the form of a database) and a more advanced way to work on transparency for standards intended to implement policy measures (e.g. the New Approach standards), more explicit selection of standards referenced in technical regulations and requirements for continuous updating of these references to standards in regulations. It would also be appropriate if these measures were aimed at improving the clarity and accessibility of regulatory requirements in the EU and the U.S., particularly for trade and industry, consumers and SMEs.

From an EU perspective, the introduction of a TBT register should be relatively easily implemented. The EU already has a developed database of draft and adopted technical regulations through the *Technical Regulations Information System* (the TRIS database).[19] TRIS is used in the context of the EU's internal notification procedure for technical regulations, which is derived from Directive 98/34/EC (the Notification Directive).[20] Expanding the register to include transatlantic agencies and draft technical regulations should yield significant transparency gains with relatively modest resources – alongside software and an implemented directive, there is also an established trust in the system. Such an expansion of TRIS can also be coordinated with a new way to link regulations to standards. Notification of technical regulations that refer to standards can, for example, be clearly marked and further linked to a contact point that provides more detailed information regarding the relevant standard and how it is referenced in technical regulations. This design

[18] Sweden applies a three-month standstill period which runs parallel with the EU's internal notification procedure for technical regulations under Directive 98/34/EC (the Notification Directive).
[19] Cf. the U.S. system for the notification of technical regulations, *Notify U.S.* (https://tsapps.nist.gov/notifyus/data/index/index.cfm). Note, however, that this study does not intend to assess the extent to which the EU and U.S. systems for notification of technical regulations are compatible.
[20] TRIS 2.0, TRIS Extranet: https://webgate.ec.europa.eu/trisextra/.

can bridge the gap that may exist between technical regulations and standards, and clarify how they relate to each other.

Besides procedures to enhance transparency, it is also possible for *standards* to be included in a possible TBT chapter. A basic premise of the TBT Agreement is that the relationship between standards and technical regulations should, wherever possible, be based on international standards. A coherent use of international standards is thus a means to improve the conditions for international trade and to avoid the emergence of the unnecessary barriers to trade forbidden by the TBT Agreement. If more agencies would use international standards when issuing regulations, the risk of regulatory differences resulting in barriers to trade would certainly be reduced. For this purpose – promoting the use of international standards – the TBT Agreement contains an annex on good regulatory practice (GRP) for the preparation, adoption and application of standards.[21] The annex is intended mainly for the bodies that produce standards, that is, the standardising bodies. The leading principles include non-discrimination, harmonisation through the use of international standards, avoidance of duplicative or overlapping standards, consensus in the preparation of standards and transparency. It is in the light of these principles that a potential TBT chapter should be analysed.

In view of the document "Building Bridges Between the U.S. and the EU Standard Systems", it is reasonably clear that the agreement on standards might, to the extent possible, be based on the TBT principles above. For example, this cooperative document emphasises that the principles of the TBT Agreement are to be observed and that the application of GRP (Annex 3) should be improved. However, it is possible to raise certain TBT-relevant aspects which can be attributed to differences between EU and U.S. standardisation systems. On the part of the EU, it is important for harmonised standards, standards developed by the European standardisation bodies as mandated by the Commission, not to have a foreclosure effect on products from the U.S. or a third country producer that do not comply with harmonised standards, but instead fulfil other equivalent standards. Under the current system alternative standards can be used as long as the producer can prove that by meeting these alterntive standards his product comply with the technical requireents of the applicable EU regulation or directive. It is also important that the European standardisation bodies, when developing standards in support of EU regulations, consider whether there already are consensus standards in the global market that can be applied in the EU. On the part of the U.S., it is important for U.S. agencies to to allow alternative standards other than the ones referenced in US rules and take international standards into account when developing technical regulations. One way to ensure the observance of international standards, as also proposed in the cooperative document, is for both European and U.S. standardisation bodies to pursue the transparent and accessible development of standards. This would also mean that relevant actors are invited to submit comments.[22]

Given the structural differences between EU and U.S. standardisation systems and each model's advantages and disadvantages, it is difficult based on the above to envisage a conflict between the standardisation model that will form the basis of TTIP and the applicable provisions of the TBT Agreement. If the duplication of standards is counteracted and international standards observed to a greater extent than before, it is instead more likely that the conditions for compliance with the TBT Agreement will be improved. However, based on a multilateral perspective, it is important that a presumably greater standardisation

[21] Annex 3 of the TBT Agreement.

[22] These issues are related to EU and U.S. views on what constitutes an international standard. More on this is found below in the section, *Horizontal regulations governing the area of TBT in the U.S.*

consensus between the EU and the U.S. does not have the effect of impairing the conditions of third-country standards for recognition and admission in the EU and the U.S.

Furthermore, it is likely that a forthcoming TBT chapter might contain provisions concerning *conformity assessment*. The TBT Agreement's principles, including non-discrimination and international harmonisation (see above for standards), also apply to conformity assessment systems. On account of these principles, it is currently unlikely that potential TBT chapters in TTIP would have a negative impact on compliance with the TBT Agreement. However, as emphasised above, it is important from a multilateral perspective that the cooperative forms negotiated between the EU and the U.S. do not impair conditions for the recognition of conformity assessment by third countries. The formulation of TTIP should in this regard be based on a synergy description, where enhanced cooperative forms between the EU and the U.S. also yield benefits for third countries through more uniform and clear methods for recognising conformity assessment.

Finally, it is important that rules on *marking* and *the free movement of goods* (sometimes referred as WTO-plus commitments) be developed. Generally, the same TBT-related consideration as described above is applicable, namely that the TBT Agreement's principles are to be observed and that goods from a third country are not to have worse conditions for market access than pre-TTIP. According to the National Board of Trade, one way to give consideration to a third country might be to have a thorough common methodology for impact assessment that takes into account the global context in the areas which are aiming for deeper regulatory cooperation.

3.2.2 Analysis of potential TBT sections and their relation to FTAs

Besides a favourable outcome for TTIP in relation to general WTO law and the TBT Agreement as described above, it is also important for TTIP to interact with free trade agreements concluded between the EU and third countries. The EU has concluded around thirty FTAs with third countries.[23] Some of these agreements also contain sector annexes that concern the TBT Agreement. When concluding an agreement with the U.S., it is therefore important to take into account the terms and conditions contained in these existing FTAs. If TTIP leads to the EU making structural changes to its regulations, there is a risk of substantial changes to agreement terms with respect to third countries. Ultimately, this could lead to these countries instituting legal proceedings against the EU for not living up to agreed obligations. These aspects are particularly manifest in the free trade agreements that have more extensive provisions in the TBT area. This may be exemplified by the free trade agreements with South Korea, Singapore and Ukraine (the latter is not yet signed). All of these FTAs belong to the new generation of free trade agreements.

The first fully negotiated free trade agreement of the new generation, and which has also entered into force, is that between the EU and South Korea. The agreement contains both a horizontal chapter on TBT and sectoral non-tariff provisions related to TBT. Although most of these provisions are based on the TBT Agreement, there are also provisions that go beyond those prescribed by the TBT Agreement, such as the FTA's rules on marking and labelling. It is important to note that, in several areas, the agreement recognises European regulations and standards that conform to South Korean safety levels. For example, in the field of electronics, the FTA implies that the previously mandatory third-party certification is as far as possible removed in favour of self-declaration (SDoC[24]), which is the system used in the EU. In the automotive field, the FTA implies that South Korea will successively begin

[23] See the Commission website: http://ec.europa.eu/trade/policy/countries-and-regions/agreements/..
[24] Supplier's Declaration of Conformity

to comply with the UNECE WP.29 Regulations, which are used for most areas within the EU and recognise on-board diagnostic devices according to European emission standards (Euro 6).

The FTA between the EU and Singapore largely follows the same structure as the agreement with South Korea. Here again, the agreement implies that EU regulations and standards have a significant impact. This is particularly true with regard to the automotive field, where the standards used by the EU and the testing of cars and car components are recognised by Singapore. The agreement text even identifies some European automotive standards as relevant international standards. In the electronics field, the agreement, as with the FTA with South Korea, prescribes that previously mandatory Singaporean third-party testing will gradually be replaced by the European model of self-declaration. The fully negotiated, but as yet unsigned, FTA between the EU and Ukraine also includes detailed formulations on the TBT Agreement. Under the agreement, Ukraine is to gradually adapt its regulations and standards to the EU acquis.

It is according to the above clear that in recent years several free trade agreements have resulted in the export of European regulatory models to other countries. The countries concluding FTAs with the EU may thus adopt regulatory amendments for approximation with EU regulations and standards. It is not very likely that corresponding developments will be seen under TTIP – the U.S. is in many respects an equal negotiating partner with the EU and has, for natural reasons, a different negotiating position to, e.g. South Korea and Singapore. On this basis, it is more probable that the EU (and the U.S.) will need to implement, if not short-term, then long-term changes in order to reconcile the regulatory systems of both parties. This could potentially result in concluded FTAs being affected in a way that causes already implemented approximation measures to become outdated and concluded agreements to decrease in influence.

It would be especially difficult for these third countries if TTIP were to involve structural regulatory changes that, together with formulations on equal treatment between European and U.S. products, would result in the imposition of competitive disadvantages on third-country companies which have adapted to older European regulations. However, it must be emphasised that it is currently difficult to see how such a scenario could become reality. Preliminary formulations on TTIP have clearly highlighted that the EU and the U.S. do not have an interest in implementing deeper structural changes in their respective regulatory systems, at least not initially. Many of the third country-amendments, which are a result of concluded FTAs, concern precisely these structural changes that, at least initially, would be difficult for TTIP to affect, such as conformity assessment mentioned in the examples above. Furthermore, it should be added that countries concluding FTAs with the EU might, in principle, have the opportunity as a WTO member to follow the development of TTIP within the framework of the transparency mechanism for FTAs.

In view of the foregoing, it is important that the potential benefits of a TTIP agreement with the U.S. are balanced against the risk of discrediting concluded FTAs. This risk should not, however, be exaggerated. The probability is fairly low that the EU will implement structural changes that could have an adverse effect on existing FTAs – at least in the short term. If TTIP were nevertheless to have such effects, it is important that interim measures are adopted which would give time for third countries to adapt their regulations. In such a situation, TTIP should also imply gains for the countries with which the EU has FTAs with, because they would gain improved trade opportunities with the U.S. in addition to those with the EU.

4. Legislative outsets between the EU and the U.S.

In order to identify potential proposals for TBT chapters in TTIP and gain an idea of how they might be effectively enforced in both the EU and the U.S., it might be helpful to highlight the legislative differences that exist between the two parties. Clarifying the conditions for how regulations are issued in the EU, and perhaps especially in the U.S., is somewhat a key matter in order to gain a clear picture of the regulatory challenges that exist and may arise in the future.[25] This part therefore aims to provide a descriptive explanation of the different regulatory systems – both in terms of constitutional and state differences, as well as a more detailed explanation of how the EU and the U.S. have horizontally regulated TBT related areas.

4.1 Constitutional differences with a bearing on regulatory cooperation

The Constitution of the United States separates power into three branches – the legislature, the executive and the judiciary. The legislature consists of Congress, which is responsible for the federal laws. Congress has two chambers: the Senate and the House of Representatives. The executive power is vested in the President, who is mandated to implement, enforce and administer the federal laws and to form a government. The judicial power is vested in the Supreme Court and the federal courts. Their task is to interpret and apply U.S. laws by ruling in the cases brought to them. The Supreme Court may also examine whether various laws are unconstitutional (known as judicial review).[26]

The Constitution of the United States is based on six fundamental principles. These are: separation of powers; checks and balances; limited government; popular sovereignty and, lastly, federalism.[27] This last principle may for several reasons be said to have a particular influence on the conditions for an effective regulatory cooperation between the EU and the U.S. The principle of federalism divides the U.S. into different political entities that are self-governing in relation to the federal government. The principle thus governs the opportunities for the federal government to implement legally binding regulations in the states, and conversely, the states' opportunities to implement state-specific regulations.

The division between the federal government and the states has an impact on how the U.S. may conclude and ratify international agreements. In a regulatory cooperation between the EU and the U.S., it is of the utmost importance that agreements between the parties have an effective impact on each side's regulatory systems – that TTIP is implemented to the full extent and at various levels of society. The way in which the U.S. incorporates international law into its own regulatory system has in simplified terms both elements of monism

[25] So far in the negotiations, the EU has expressed difficulties in gaining a clear overview of how the U.S. legislative system functions within the framework of the TBT Agreement. The National Board of Trade has therefore devoted particular focus to gaining a clear picture of the U.S. regulatory system.
[26] Constitution of the United States, see http://www.senate.gov/civics/constitution_item/constitution.htm.
[27] See, for example, Article 1, Section 2 of the Constitution of the United States.

(concluded agreements automatically become national law) and of dualism (a ratification measure is necessary for a concluded agreement to apply nationally). Agreements concluded in accordance with the Constitution of the United States automatically become U.S. law. For that to happen the approval of two thirds of the Senate is required.[28] However, most international agreements concluded by the U.S. are not adopted in accordance with the Constitution in the monist manner, but are implemented through "normal" federal legislation by Congress (a majority in both the House of Representatives and the Senate).[29] There are also instances of the President signing executive agreements on the basis of prior approval by Congress.[30]

After TTIP has become law in the U.S., through one of the means mentioned above, the question arises on how the Agreement can have an impact on state level. An initial observation is that the U.S. states are states within the framework of a sovereign state, which may be compared with the European Union, which consists of sovereign Member States, but which have given parts of their power to the EU. It is in a comparison between these legal actors – the U.S. federal state, the EU, the states and the Member States – that it is possible to gain an overview of how cooperation can be formed in practice.

In the constitutional context, there are several grounds of comparison between the U.S. states and the EU Member States that are important from a TTIP perspective. First, the states must abide by the *dormant commerce clause*. The doctrine of the dormant commerce clause forbids states to act in ways that impede interstate commerce. Improper restrictions and discrimination of, e.g. other states' products, is thereby prevented by the doctrine. In other words, the doctrine can very roughly be described as the U.S. counterpart to the EU Treaty principle of free movement. Not infrequently, the doctrine entails setting particular federal state interests, e.g. the introduction of higher environmental standards, against the interest of other states in maintaining a common internal market. Disputes touching upon this doctrine are treated by federal courts under the Constitution's commerce clause.[31] From a TTIP perspective, the doctrine could in principle be able to have the effect of products that have gained market access in one state also being able to gain this in other states. In this way, a transatlantic free-trade area would benefit from the doctrine as far as possible being made available to European goods.

Another important doctrine is, secondly, that of the federal state's supremacy over the states. This doctrine is based on the Constitution's *supremacy clause* and means that state laws that conflict with federal law shall be considered ineffective. Within the framework of the supremacy clause, the *pre-emption* doctrine has evolved. From an EU perspective, this doctrine may be compared with the principle of primacy of EU law, the principle of subsidiarity and, to some extent, the principle of sincere cooperation – EU principles that regulate the hierarchy of norms between the EU and its Member States. Typical situations when the doctrine is applied are when Congress introduces laws that in some respects are contrary to state laws or prevent their entry into force.[32] The doctrine thus has a centralising effect, which from a TTIP perspective could, for example, limit the fragmentation of product regulations at the state level. Note, however, that the doctrine is debated as it raises fundamental questions about the autonomy of states in relation to the federal government. It is thus questionable whether U.S. state law can be affected by international agreements.

[28] Article II of the U.S. Constitution.
[29] Akehurst's Modern Introduction to International Law, pp. 66-67.
[30] Smith, Shedd and Murrill, *Why Certain Trade Agreements Are Approved as Congressional-Executive Agreements Rather than Treaties*, Congressional Research Service 2013, p. 1.
[31] Vogel and Swinnen, Transatlantic Regulatory Cooperation, pp. 5-8.
[32] Vogel and Swinnen, Transatlantic Regulatory Cooperation, pp. 8-9.

Thirdly and finally, the *pre-emption* doctrine applies in situations when the President or Congress implements non-legislative measures that have a bearing on foreign policy. This may be a case of situations when the federal government, for example, concludes an international agreement that indirectly entails that states cannot act in a certain way and in violation of that agreement. A state is in other words prevented from acting under this domain.[33] The pre-emption doctrine might in this respect have an impact on the conditions for TTIP, as the doctrine's centralising effect would prevent states from taking measures in violation of TTIP, e.g. through regional agreements with foreign regions.

This account demonstrates that there are some "constitutional" similarities and differences between the EU and the U.S. that make it possible to obtain a descriptive overview of how the different systems could operate under TTIP. Naturally, it would be attractive to compare the EU and the U.S. as each other's counterparts, and in many ways this would facilitate an analysis of how TTIP should be designed and implemented. Nevertheless, it is important to emphasise that there are differences between the EU and the U.S. that affect how TTIP might function.

In the U.S., the states are part of a federal state, which means that international agreements concluded by the federal government may to some extent be seen as impositions from above, the pre-emption doctrine being an example of this. In the EU, the Commission acts on the mandate of the Member States and the European Parliament. The Member States are actively part of the TTIP process and act on the basis of it being an agreement to which they as sovereign states are aspiring. This means that although the U.S., due its federal context, is superficially able to implement measures in a more powerful way, this does not necessarily mean that there cannot be difficulties in getting an agreement of this scope to have a real impact at the state level. On the other hand, an implementation of TTIP in the EU is based on other premises and is, superficially in U.S. eyes, a complex process whereby the Member States themselves implement the agreement in their national legal systems – with the natural risk that implementation becomes fragmented and disjointed between the countries.

These differences illustrate the dynamic processes that TTIP involves, and it is with an awareness of each other's regulatory similarities and differences that TTIP can be developed according to the best conditions and gain a broad impact. The next section therefore aims to clarify how technical regulations are managed in the U.S. and how this management differs from that in the EU.

[33] Vogel and Swinnen, Transatlantic Regulatory Cooperation, pp. 9-11.

4.2 Horizontal regulations governing the area of TBT in the U.S.

4.2.1 Technical regulations

In the U.S., horizontal TBT aspects are governed through the *Administrative Procedure Act of 1946* (APA) and the *Trade Agreements Act of 1979* (TAA). In brief, the APA establishes procedures to bring about public participation when government agencies are developing new regulations. The procedure sets requirements on the issuing of new regulations and provides the public with the opportunity to submit views on the proposals issued. The APA constitutes the basis for the transparency of federal regulations and prescribes requirements that U.S. agencies must publish their draft technical regulations and conformity assessment procedures in a federal register that is accessible to the public.[34] The TAA prohibits federal agencies from introducing requirements that create unnecessary barriers to trade and encourages the agencies to make use of international standards when issuing regulations. The TAA also identifies the federal *Office of the United States Trade Representative* (USTR) as the agency responsible for coordinating and developing trade policy on technical regulations at the federal level.[35]

Furthermore, however, it is the agency *the National Institute of Standards and Technology* (NIST) that notifies technical regulations and conformity assessment procedures to the WTO under the TBT Agreement. NIST is part of *the Department of Commerce* and is also the TBT Enquiry Point for the U.S. Accordingly, NIST reviews the Federal Register, where draft rules are posted, and examines whether notification under the TBT Agreement is necessary.[36] NIST is responsible for the U.S. database of technical regulations, *Notify U.S.*, where stakeholders can consult and comment on notifications of technical regulations.[37]

Good regulatory practice (GRP) is governed by the act *Executive Order 12866 – Regulatory Planning and Review*. The act stipulates the regulatory starting points and principles that federal agencies must follow when they plan, prepare and review federal rules. The procedure ensures openness, transparency and accountability among federal agencies. There is also an instruction, *Circular A-4*, produced by *the Office of Management and Budget* (OMB), which aims to make it easier for agencies to develop rules so that they can effectively achieve the stated regulatory objectives while observing that these rules do not create unnecessary barriers to trade. When developing a “significant regulatory action”, a specific procedure for judicial control is applicable. Significant regulatory actions are defined as rules that are expected to have an annual effect on the U.S. economy of at least USD 100 million. In these situations, the federal agency must notify its proposal to OMB, which in turn consults with USTR on the proposal's impact on international trade. OMB then submits an advisory opinion on how the proposal relates to applicable law, the President's priorities and the act *Executive Order 12866 – Regulatory Planning and Review's* GRP-conditioning principles.[38] The different regulations for the judicial control of federal rules and GRP have on several occasions been subject to additions in order to better achieve various U.S. policy objectives – such as the promotion of simpler rules and the removal of regulatory burdens. In connection with similar measures, action has been taken to improve

[34] The *Federal Register* website: https://www.federalregister.gov/.
[35] 2013 Report on Technical Barriers to Trade, United States Trade Representative, p. 19.
[36] 2013 Report on Technical Barriers to Trade, United States Trade Representative, p. 19.
[37] See, https://tsapps.nist.gov/notifyus/data/index/index.cfm.
[38] 2013 Report on Technical Barriers to Trade, United States Trade Representative, p. 20.

the impact of standards in agency regulations. The *National Technology Transfer and Advancement Act* (NTTAA) and OMB *Circular A-119* are examples of statutes that encourage the use of voluntary consensus standards in technical regulations and advise against the agencies' use of agency-unique standards.

In the EU, notifications of technical regulations to the WTO are managed on the basis of the division between harmonised and non-harmonised legislation. In the harmonised area, the Commission notifies draft technical regulations.[39] In the non-harmonised area, the Member States are responsible for notifying draft technical regulations. In Sweden, for example, the National Board of Trade notifies technical regulations under the Governmental Ordinance (1994:2029) on Technical Regulations. It is through consensus on these horizontal regulations, in the EU and the U.S., that transparency between the parties can be achieved. It is important to note that the European division of notifications between the Commission and the Member States has been perceived by American colleagues as complex and difficult to understand.[40] Clarification and simplification measures may need to be taken on the EU side to facilitate greater transparency. Corresponding U.S. measures may also become necessary, particulary with regard to transparency at the state level.

4.2.2 Standards and standardisation

Standards can generally be described as gaining great significance for TTIP, and it is very important that it is possible to find entry points for cooperation in this area. This is because many technical regulations and requirements on conformity assessment procedures are based on standards. This may, for example, be a question of technical definitions, criteria and procedures that to various extents will guide agencies as they issue regulations.[41] If EU and U.S. standards are designed differently, this automatically weakens the conditions for the mutual functioning of the regulations affected by standards. The structural differences between the EU and U.S. standardisation systems must therefore be bridged if the two systems are to be compatible and mutual benefit be drawn from each other's systems.[42] The following mentions some differences that are particularly important to consider.

In the U.S., standardisation is market-driven and heavily decentralised.[43] Standards (known as Voluntary consensus standards) are developed primarily by private actors (including Standards Developing Organizations, SDOs) in various industrial sectors in response to the demand of industry, agencies and consumers for standards. Standardisation is open to different actors, and standards can be developed without the requirement of compatibility with existing standards. Agencies are free to adopt the standards they consider best suited for the purpose. Since the mid-1990s, standards have also gained increasing influence at U.S. government agencies, and many regulations now refer to standards. Standards have also increased their influence in a variety of policy areas (see the NTTAA example above) and the U.S. strategy for standardisation.[44] In addition to *the American National Standards*

[39] DG Enterprise and Industry, Unit C3.
[40] The Commission's opinion at the TBT Committee meeting in Brussels on 14 October 2013.
[41] Standards that are developed in order to relate to legislation are in the EU considered formal standards. In the U.S., there is no clear distinction between formal and non-formal standards.
[42] See on this subject the document, *Building Bridges Between the U.S. and EU Standards Systems*, available from the following website: http://www.whitehouse.gov/sites/default/files/omb/oira/irc/us-eu-standards-bridges.pdf.
[43] 2013 Report on Technical Barriers to Trade, United States Trade Representative, pp. 24-25.
[44] Over 4000 officials at federal agencies are currently involved in standardisation activities. Ibid.

Institute (ANSI), which is the coordinating U.S. standardisation body, there is the federal agency NIST, which cooperates with ANSI.[45]

Standardisation within the EU is in principle based on European standards (known as EN standards) and harmonised standards. A material difference to the U.S. system is that in the EU, there are three standardisation bodies, CEN, CENELEC and ETSI, which are identified as European standardisation bodies.[46] In order for a standard to be counted as a "European standard", the standard must have been produced by one of these three bodies. In other words, standardisation in the EU is centralised and non-competitive, while in the U.S. it is competitive, where different standardisation bodies compete to produce the most suitable standard for a given purpose.[47] European standardisation bodies can be regarded as regional standardisation bodies in accordance with the TBT Agreement. Membership in relation to other WTO Members is limited while it at the same time is possible for different stakeholders to be part of the standardisation process.

In this regard, the European standardisation bodies CEN and CENELEC have signed agreements with their respective international and non-regional counterparts, the International Standardization Organisation (ISO) and the International Electrotechnical Commission (IEC), setting out the rules governing co-operation. The main objectives of the Vienna Agreement (ISO-CEN) and the Dresden Agreement (IEC-CENELEC) are to provide a framework for the optimal use of resources and expertise available for standardization work and facilitate a mechanism for information exchange between international and European Standardization Organizations (ESOs) to increase the transparency of ongoing work at international and European levels. The Vienna Agreement signed in 1991, was especially drawn up with the aim of preventing duplication of effort and reducing time when preparing standards. As a result, new standards projects are jointly planned between CEN and ISO. Wherever appropriate priority is given to cooperation with ISO provided that international standards meet European legislative and market requirements and that non-European global stakeholders also implement these standards.[48]

Furthermore, harmonised standardisation means that the European standardisation bodies can be requested by the Commission to develop standards in support of compliance with EU legislation. Products developed according to a harmonised/EN standard will be presumed to possess conformity with general product requirements specified in EU secondary legislation and thereby gain access to the EU internal market. Other standards may also meet the technical requirements of EU legislation, but they cannot have presumption of conformity with the specified product requirements.[49] In addition to this, there is also a different view between the EU and the U.S. on the issue of what is to be regarded as an international standard. The issue has a bearing on how the TBT Agreement is to be interpreted and what effect the agreement will have. Technical regulations that are consistent with an international standard are by definition not a barrier to trade. A broad interpretation of the TBT Agreement may mean that national technical regulations gain WTO conformity to a greater extent, regardless of their impact on international trade. The U.S. stance on the issue is that the TBT Agreement does not define international standardising bodies, and that the primary guideline that exists is the "*2000 Decision on Principles for the Development of International Standards, Guides and Recommendations (2000 Committee Decision)*". If standards are developed in accordance with the guidelines, they are, according to the U.S., to

[45] See the ANSI document, "Overview of the U.S. Standardization system", Second Edition 2007.
[46] See Regulation 1025/2012 on European standardisation.
[47] See the CEN website: http://www.cen.eu/cen/products/en/pages/default.aspx.
[48] See http://www.cencenelec.eu/intcoop/StandardizationOrg/Pages/default.aspx.
[49] See the CEN website: http://www.cen.eu/cen/products/en/pages/default.aspx.

be considered international.[50] The EU's stance on the issue is that the TBT Agreement does indeed define what constitutes an international standardising body (Annex 1.4) and that the agreement presupposes that membership is open to bodies from all WTO members. According to European regulatory system, currently ISO, IEC and ITU satisfy this definition. Thus, it is only standards issued by these bodies that can be classified as international in the sense of the TBT Agreement.[51]

The starting point for any attempt to harmonise EU and U.S. standardisation systems makes this a difficult task. The structural differences are considerable in several respects. Both systems have their advantages and disadvantages and are founded on different premises. From a U.S. perspective, there are several arguments to suggest that the EU system is less well suited for an international context since only *one* standard is permitted to give presumption of conformity with binding product requirements in EU legislation. From an EU perspective, the U.S. system has its limitations since it is unclear on what basis a standard is choosen for referens and usually, the referenced standard or standards, are mandatory in the sense that alternative ones cannot be used by the producers. It is unclear what would happen if the U.S. standardisation system was applied by other countries due to this entailing the weakening of existing structures[52]. Which scenario would, for example, apply if different standardisation bodies from different countries or trading blocks were to expressly start competing with each other, and is this then more constructive than if the standardisation bodies mutually co-operate with each other on the basis of their clearly defined positions (through formal standardisation)? These questions reflect what is at stake if a lasting change in the standardisation area is to be achieved.

4.2.3 Conformity Assessment

In the U.S., it is the NTTAA which requires NIST to coordinate conformity assessment at federal, state and local agencies with standards and conformity assessment in the private sector. The goal of coordination is to avoid the duplication of tests between different actors involved in conformity assessment procedures. NIST has published a guidance document in the *Federal Register*, which advises federal agencies, for example, to rely on assessments made by other government and private actors and to make use of international guidance and standards when implementing requirements on conformity assessment procedures in technical regulations and when conducting procurements. ANSI also provides guidance for federal agencies and private actors on conformity assessment procedures.[53]

U.S. accreditation bodies participate in procedures for mutual recognition under the *International Laboratory Accreditation Cooperation* (ILAC) and the *International Accreditation Forum* (IAF), known as MLAs. These accreditation bodies are in the first instance private actors. However, more and more federal agencies are making use of international systems such as ILAC to underpin their requirements for conformity assessment.[54]

[50] 2013 Report on Technical Barriers to Trade, United States Trade Representative, pp. 24-25.
[51] See the definition of international standardisation body in Regulation 1025/2012, Article 2 (9), and the opinion of CEN and CENELEC on TTIP. See CEN identification number in the Transparency Register: 63623305522-13.
[52] This refers to the special status of the international standardisation bodies through that which the EU calls formal standardisation.
[53] 2013 Report on Technical Barriers to Trade, United States Trade Representative, p. 27.
[54] 2013 Report on Technical Barriers to Trade, United States Trade Representative, p. 28.

In the EU, conformity assessment is defined by Regulation 765/2008 and Decision 768/2008/EC as "the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled". A conformity assessment body, according to the same statutes, is "a body that performs conformity assessment activities including calibration, testing, certification and inspection". Furthermore, the European system is based on 'Notified Bodies', which carry out conformity assessment against certain EU Directives and thereby harmonised standards according to the New Approach. Businesses that are accredited and notified may test and verify products in competition with each other in a free market. In Sweden, it is Swedac[55] that assesses and appoints notified bodies.[56]

Swedac is also the appointed Swedish accreditation body under Regulation 765/2008. Accreditation can be described as a statement from an independent third party that a conformity assessment body is competent for the task. In the EU, every national accreditation body must be a member of the *European accreditation organisation* (EA[57]) and must undergo reference assessments organised by the EA. They must also be members of international accreditation organisations (IAF[58]/ILAC[59]). The EA, in its turn, has regional agreements with other regional accreditation bodies. It is between these bodies that there are agreements on mutual acceptance, MLAs, and reference assessment systems.

There are certain differences between the EU and the U.S. regarding conformity assessment and accreditation. In the EU, accreditation bodies are government agencies, and there is only one accreditation body in each country[60]. In the U.S., there are several bodies that perform accreditation in competition with each other. There may thus be different views on the role of accreditation bodies, but in principle the technical content should be the same. When the European regulatory framework was introduced, there was a request made by the companies accredited in many parts of the world for the development of a simpler system – a mechanism for mutual recognition – and for third-country activities to be subsumed under a European accreditation. This can still be described as an ongoing discussion that is difficult to resolve. Within the framework of the WTO's TBT Committee, the U.S. has asked the EU how the new EU Regulation on accreditation will affect relations between the U.S. and European markets. In practice, the different systems have functioned *relatively* well, and there is mutual recognition between the two systems.[61] Recognition of the parties' conformity assessment is accordingly based on the accreditation of the parties' conformity assessment bodies by bodies recognised under the prevailing MLA. To the extent that prevailing systems work well, measures are advocated that strengthen the existing structures and enable simplified procedures for mutual recognition.

[55] Swedish Board for Accreditation and Conformity Assessment.
[56] See the Swedac website: http://www.swedac.se/sv/Omraden/Anmalda-organ/.
[57] European co-operation for Accreditation.
[58] International Accreditation Forum.
[59] International Laboratory Accreditation Cooperation.
[60] This derives from Regulation 765/2008/EC.
[61] Presentation by Swedac on 18 September 2013 at the National Board of Trade's meeting with the Contact group for technical regulations and barriers to trade. For further distinctions, compare conformity assessment in the section *Regulatory tools for managing TBT and in-depth analysis* and the sector section *ICT*.

5. Regulatory tools for managing TBT and in-depth analysis

The National Board of Trade has carried out many studies aimed at identifying different tools to deal with technical barriers to trade. One of the most important is the analysis *Arrangements to Avoid Technical Barriers to Trade*[62], which presents methodological points of departure to avoid or eliminate technical barriers to trade.

The foundation of an open trade regime is a good regulatory practice at the national level that underlines transparency and openness.[63] The key is, already in the design of technical regulations, to undertake regulatory impact assessment through broad consultation with the parties concerned. Regarding the EU's dialogue with major trading parties, the emphasis should be on creating a profound understanding of the other party's regulations and requirements. There are different ways to achieve regulatory cooperation. The regulatory tools to be considered can be understood in relation to the desired *level*[64] of rule transparency according to the following matrix[65]:

[62] Ref no 160-0850-2010. See also: *Samarbetsformer för att överkomma transatlantiska handelshinder* [Cooperative forms to overcome transatlantic barriers to trade], Ref no 2011/00167.
[63] In practice, this means that agencies at the national level perform impact assessments on the regulation they have developed and intend to propose and allow easy access to information on this regulation.
[64] Levels 1-2 are characterised by national measures in the form of good regulatory practice (GRP), while levels 3-6 involve various levels of transnational arrangements in the form of regulatory cooperation.
[65] Note the following when reading the matrix; *Multilateral Agreement* (MLA), *Mutual Recognition Agreement on conformity assessment* (MRA), *Good Laboratory Practice* (OECD GLP), *Agreements on Conformity Assessment and Acceptance of Industrial Products* (ACAA), *Protocols to the Europe Agreements on Conformity Assessment and Acceptance of Industrial Products* (PECA).

Type of activity	Different Degrees of Regulatory Co-operation	Example of agreement
National practice ("Good Regulative Practice")	1.**Information exchange procedures/transparency measures**	• WTO/TBT-Agreement • Directive 98/34/EC, • Regulative dialogues
	2.**Observance of principal trade policy provisions** **-** non-discrimination, proportionality, performance based regulations, use of international standards etc.	• TBT, GATT, FTA, • EU New Approach, • UNECE-recommendations
Trans-national arrangements ("Regulative Co-operation")	**3.Recognition of conformity assessment procedures** - common procedures (testing procedures, test report forms) - accreditation systems	• MLA
	4. Recognition of results of conformity assessment procedures - certificates of conformity - inspections - test results	• MRA • OECD: GLP
	5.Recognition of (functional) equivalence technical regulations -product specifications (essential requirements and standards linked to those requirements) - marking specifications, marks etc.	• ACAA • PECA • UNECE "International Modell" • EU-South Korea FTA/ Sectoral annex on Automotives • EU-USA MRA Marine Equipment
	6. Recognition of fully harmonized technical regulations	• EU harmonized area

The lowest level requires information exchange and transparent regulations. From the point of view of the National Board of Trade, various forms of procedures for information exchange have also been the most viable way to counteract technical barriers to trade on the transatlantic market. Such procedures require, however, that regulatory initiatives are communicated at a very early stage. At the same time it must be taken into account that the preparation, adoption and implementation of regulations might take time. On the horizontal level, the question is whether a new procedure within TTIP, in addition to that already existing within the WTO for the notification of technical regulations, and in EU Directive 98/34/EC, can be considered justified. The answer can tentatively be found in sectoral transparency mechanisms. However, mechanisms of this kind have not yet been established between the regulatory agencies in the sectors analysed in this study. On the other hand, the goal of establishing such mechanisms has been the subject of discussion, for example, in the area of chemicals.

Mutual recognition of regulations is, as a concept, a feasible way to reduce TBT-related barriers. Recognition can apply to material requirements for products or services, but also, for example, to conformity assessment bodies and test results. Provisions for mutual recognition mean that the respective party does not in principle need to make any changes to its material rules. Recognition is instead accorded to each other's rules as being equivalent and hence mutually acceptable. Mutual recognition in such a form is however seldom implemented without additional requirements and arrangements.[66]

[66] The concept of mutual recognition in the EU non-harmonized area and MRA on conformity assessment, are good examples.

The other regulatory levels in the matrix thus presuppose recognition of approval procedures (conformity assessment procedures) or recognition of the results of approval procedures (results of conformity assessment procedures). However, experience from MRA[67] shows that such arrangements are difficult to negotiate and implement since such arrangements require both product requirements and conformity assessment systems to be comparable.[68] Based on previously concluded MRAs between the EU and the U.S., for example on electrical safety, it is obvious that there was a lack of will to respect entered commitments.[69] It has also been found that the U.S., when applying existing MRAs (electrical safety and telecommunications), uses federal rules to create additional requirements that go beyond the internationally accepted procedures for conformity assessment.[70] These requirements do not only result in requirements for products, but also lay down specific requirements for accreditation bodies, for technical assessors, for obligations to participate in meetings with federal agencies in the U.S. and reporting obligations.[71] These additional requirements are not transparent and are often only discovered upon implementation.[72] The positive aspect for trade and industry is that products can be put on the U.S. market without undergoing product certification in the U.S., and that, e.g. electromagnetic compatibility certificates (EMC

[67] Mutual Recognition Agreements (on conformity assessment). Agreements between two parties for mutual recognition of procedures to assess the conformity of goods with the other party's technical regulations. These agreements mean that the exporting party can perform the procedures – testing, certification, marking etc. – required to assess whether a product (for example pharmaceuticals, machinery, electrical goods) is consistent with the importing party's regulations. An example might be U.S. agencies certifying that recreational boats manufactured in the U.S. meet EU requirements before they are exported to the EU.

[68] The MRA on marine equipment is an exception, however. As the MRA in the area is based on international rules (IMO), it has been easier to implement the agreement in practice.

[69] See the National Board of Trade inquiry, *Samarbetsformer för att överkomma transatlantiska handelshinder* [Cooperative forms to overcome transatlantic barriers to trade], Ref no 2011/002167.

[70] The counterpart of the Swedish agencies, the Swedish Post and Telecom Authority and the National Electrical Safety Board, the *Federal Communications Commission* (FCC), provides a checklist for assessment in the EMC area that is mandatory to assess against and contains additional requirements and methods from ANSI that go beyond the accreditation standards for laboratory assessment ISO/IEC 17025.

[71] Swedac believes that accreditation bodies should not be treated as private enterprises and that the bodies should not be required to have branches in the U.S. The accreditation bodies are not performing accreditation in the U.S. Instead, there is a need for more trust from agencies in the U.S. It is important to note that accreditation bodies in Europe are government agencies and not private enterprises as in the U.S. and, as such, they are not commercial but act as the state's extended arm. In this regard, it would be desirable if the U.S. could rely on the EA's MLA agreement, which is an agreement between agencies based on reference assessment and joint international standards.

[72] For example, Swedac has examined forthcoming U.S. requirements concerning rules for emissions of formaldehyde in composite wood products. In order for products to be placed on the U.S. market, they must be certified by an accredited product certification body. The accreditation is to be performed by accreditation bodies that are approved and have an agreement with the *Environmental Protection Agency* (EPA). The requirements are extensive, and even if one refers to ILAC/IAF agreements, these are not sufficient. The accreditation body shall, among other things, have an agent in the U.S. as a communication link between the EPA and the accreditation body. Swedac can understand the purpose of this, but also believes that this can be resolved in other ways. In Sweden, it is important that those who are accredited against government agency regulations remain updated on developments and that Swedac in its capacity of accreditation body also acts so that it always makes assessments against the latest applicable regulations. For Swedac, this is natural and should be able to be resolved without an agent. It would have been desirable if everyone could rely on the accreditation systems that exist.

certificates) from the conformity assessment bodies are accepted in the U.S.[73] The precise market advantage that companies gain under existing agreements is somewhat difficult to quantify – some actors make use of certification services in the U.S. and do not utilise MRAs. It may, however, be confirmed that the services of the two bodies that perform conformity assessment under the existing MRA in Sweden are in demand by the industry.[74] With respect to other potential areas, such as medical devices, Swedac notes that the U.S. works against extremely detailed rules, even if accreditation standards are essentially used. As an accreditation body working for international rules, Swedac views it as troubling if a country cannot accept an established system. This creates problems both for accreditation bodies, manufacturers and for those who assess conformity. Global consensus on product rules would of course eliminate such problems.

It is well known that the ambition applied to the EU's internal market with the (full) harmonisation of rules, i.e. the highest regulatory level in the matrix, is the most effective method of avoiding technical barriers to trade. However, harmonization is a long and expensive process that also requires a common legislative framework and consensus on underlying technical regulations, standards, conformity assessment procedures and enforcement (market surveillance). It therefore appears that harmonisation is not a viable option in the transatlantic dimension, especially considering the existing regulatory models (between the EU and Member States and at the federal and state levels in the U.S.). With regard to functional harmonisation – which assumes agreement on the overarching regulatory goals but not the means of achieving them – would also not appear to lend much support to transatlantic trade. This is because it is above all approval procedures and enforcement of products by regulatory authorities that differ between the markets. The focus should rather be on the recognition (acceptance) of equivalent technical regulations and standards. Whether or not this can be agreed upon depends in turn on whether it is possible to establish specific EU rules as comparable to those in the U.S., not only in function but also, for example, in terms of environment and other aspects. This is exactly where the greatest challenge lies. Goods are rarely affected by *one* system of rules, but by multiple regulatory areas, not least with regard to cross-border requirements for the environment, sustainability and various national security interests. Another fact that should probably also be considered in this context is that the regulatory model currently used in different sectors, both in the EU and the U.S., creates competitive market conditions, not only in form of health and safety, but also in form of product quality. Thus, changing the current regulatory model may entail the removal of unique product characteristics in the form of market profileration.[75]

Based on the experience we have today, it may however be concluded that there is a lot to gain by using international regulations and standards, and as far as possible, working towards these in areas where international rules and standards have not been implemented. The sectors where most progress has been made in terms of technical harmonisation are precisely those applying international regulations, such as the *International Maritime Organisation* (IMO) for shipping and UNECE WP.29 for vehicles. However, international regulations only exist in a limited number of areas.

The need for national and regional regulation (and protection levels) appears to remain an important matter in individual countries throughout the world. This is not least confirmed by

[73] Swedac, *Statement*, Ref no 2013/3692.
[74] *Svenska Elektriska Materielkontrollanstalten* (SEMKO) and *SP Technical Research Institute of Sweden* (SP).
[75] However, in the context of the present study, it has not been possible to analyse this aspect in more detail.

the increasing number of technical barriers to trade.[76] Technological development and globalisation also generate new technical barriers to trade, especially in areas where countries cannot agree on common standards and regulations. One example of this is the requirements in the field of information security in ICT and telecommunications. These consist of requirements that are legitimate to regulate (national security interests) but that easily create barriers in the form of various, differing product requirements and approval procedures.

Existing regulatory tools used between the EU and the U.S. thus consist of a variety of regulatory dialogues and of actual operational MRAs (effective since 2000) in the areas of recreational boats, EMC and telecommunications. MRAs have, as previously stated, been deemed questionable from a cost-benefit perspective.[77] Regulatory dialogues in their turn have proved insufficient to establish permanent structures through which the objectives of regulatory approximation could be accomplished.

It has so far been difficult to form a clear picture of the the transatlantic regulatory dimension. It has also been challenging to elucidate how various initiatives relate to each other. The complexity of technical barriers to trade is not only linked to the fact that the regulations often have a legitimate purpose, but also to the fact that many technical barriers to trade arise outside the direct control of states. Industry associations and standardisation bodies for example regularly set conditions that affect the trade in goods and services.

Which regulatory instrument that should be used for approximation between the EU and the U.S. should thus be set in relation to the situation, the differences found in the parties' regulatory frameworks, a consideration of existing international rules and standards, and the volume of trade in the area or sector considered. Work on technical barriers to trade is long-term and often leads to protracted negotiations. It is therefore of the utmost importance to perform a thorough evaluation of the level of ambition based on desired results and the expected economic potential of the planned measure(s).

The National Board of Trade cannot see *one* tool or *one* level of regulatory cooperation as being able to resolve barriers horizontally – rather, the parties will have to adapt the level of regulatory approximation to the area where there is a desire to resolve existing problems or to create conditions for future joint regulation. However, it seems reasonable for transatlantic regulatory approximation to demand explicit channels for bilateral dialogue, that is, forums where the specific regulatory interests may find expression. Also a process is needed that enables an objective assessment of existing and future regulations, with equal representation from both parties. Besides this, there must be an explicit mandate for the work that binds the parties to respect concluded agreements and a system for dispute settlement. The work must also be able to take into account and evaluate regulatory impact, especially in areas that currently lack uniformity at the Member State level in the EU and at the state level in the U.S.[78]

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[76] See G/TBT/33: *Eighteenth Annual Review of the Implementation and Operation of the TBT Agreement*, 27 February 2013, WTO TBT Secretariat.

[77] Of the six concluded agreements on mutual recognition, three failed to become operational within the specified time limits. While the U.S. was reluctant to accept European assessment, the implementation on the European side was dependent on the Member States, which resulted in a lack of uniformity in implementation and results. Both sides also adopted extensive regulatory legislation (REACH/Sarbanes-Oxley) in violation of the guidelines for regulatory cooperation. This led to widespread criticism. See also the section, *ICT*.

[78] One forum where it has been possible to reach agreement on *Common Regulatory Objectives* (CRO) in limited areas is UNECE WP.6 that has used the International Model for Technical Harmonisation. However, the weakness of the system is that it is not legally binding on any party. See: http://www.unece.org/fileadmin/DAM/trade/wp6/Recommendations/Rec_L.pdf.

6. Analysis of five sectors: Automotive, information and communications technology, chemicals, pharmaceuticals and medical devices

6.1 Swedish and EU trade with the U.S. – a statistical perspective on the five sectors

According to Statistics Sweden[79], Swedish exports to the U.S. amounted to 75.0 billion SEK in 2012. Imports of goods from the U.S. in the same year amounted to 36.5 billion SEK. To make it possible to compare the statistics for Sweden and the EU as a whole, the tables below use statistics from Eurostat[80], expressed in billions of euros. According to Eurostat, Swedish exports to the U.S. in 2012 amounted to 8.6 billion EUR and imports to 4.2 billion EUR and expected financial potential in the planned measures.

While chemicals, pharmaceuticals and automotive are fairly easy to identify in the classification of international trade statistics, medical devices and ICT pose greater challenges. The tables below use the fourth version of the *System of International Trade Classification* (SITC Rev. 4). Chemicals constitute the overarching commodity group *5 – Chemicals and related products, n.e.s.* and pharmaceuticals, a subgroup of the chemicals industry, constitutes *54 – Medicinal and pharmaceutical products.* Automotive consists of the commodity group *78 – Road vehicles (including air-cushion vehicles).* Thus, this does not include e.g. aircraft or ships.

The definition of what is included in the group medical devices has been taken from the *Dental and Pharmaceutical Benefits Agency* (TLV).[81] In addition to the commodity groups that have the most obvious connection to medical devices, *774 – Electrodiagnostic apparatus for medical, surgical, dental or veterinary purposes, and radiological apparatus* and *872 – Instruments and appliances, n.e.s., for medical, surgical, dental or veterinary purposes*, TLV has also chosen to include groups *871 – Optical instruments and apparatus, n.e.s.* and *884 – Optical goods, n.e.s.*, which both contain medical devices. The reported statistics thereby risk somewhat overestimating the trade in medical devices. The definition of the commodity group Information and communications technology is more complicated, and the definition has evolved and changed over the years. The definition used here is from the OECD Information Technology Outlook 2010.[82] The commodity group consists of six main groups: electronic data processing (EDP) equipment; office equipment; control and

[79] See the National Board of Trade's trade statistics fact sheets; www.kommers.se/statistikblad.
[80] Eurostat - Easy Comext - http://epp.eurostat.ec.europa.eu/newxtweb/.
[81] Dental and Pharmaceutical Benefits Agency; Slutrapport – Regeringsuppdrag att göra hälsoekonomiska bedömningar av medicintekniska produkter; Ref no 1279/2012; p. 78. http://www.tlv.se/Upload/Medicinteknik/Slutrapport_for_synpunkter_medicinteknik.pdf .
[82] OECD Information Technology Outlook 2010 – Annex A, p. 287 - http://www.keepeek.com/Digital-Asset-Management/oecd/science-and-technology/oecd-information-technology-outlook-2010_it_outlook-2010-en#page281. Translation from HS2007 to SITC Rev. 4 used the correspondence table from the UN: http://unstats.un.org/unsd/trade/sitcrev4.htm.

instrumentation; radio communications (including mobiles) and radar; telecommunications; consumer equipment; and components. It should be noted that the groups medical devices and ICT to some extent overlap and should therefore not be combined. The tables below present commodity trade with the U.S. for both the EU and Sweden. The statistics for the EU are not adjusted for the Swedish contribution. The tables show the five requested commodity groups' value and percentage share of total exports and total imports for U.S. trade with the EU and Sweden, respectively. The comments focus mainly on the figures for 2012.

6.1.1 Exports

Tables 1 and 2 below present U.S. commodity exports from the EU and Sweden in terms of value and as a share of total exports. The figures thus show the commodity group's importance for exports to the U.S.

Table 1. Exports to the U.S. from the EU and Sweden
Value (EUR billions)

	EU					Sweden				
	2008	2009	2010	2011	2012	2008	2009	2010	2011	2012
Chemicals	52.7	53.5	60.3	62.1	66.7	1.3	1.1	1.2	1.3	1.4
Pharmaceuticals	24.4	27.3	30.4	30.6	32.9	1.0	0.9	0.9	0.9	0.9
Automotive	27.0	17.4	25.0	26.9	34.0	1.2	0.7	1.0	0.9	0.8
Medical devices	8.3	7.5	8.1	8.8	9.0	0.1	0.1	0.2	0.2	0.2
ICT	16.4	14.0	17.3	17.3	18.4	0.8	0.7	2.1	1.0	1.1
Exports total	247.8	203.6	242.4	263.8	292.5	8.2	6.0	8.8	8.5	8.6

Table 2. Exports to the U.S. from the EU and Sweden
Shares of total exports to the U.S. (%)

	EU					Sweden				
	2008	2009	2010	2011	2012	2008	2009	2010	2011	2012
Chemicals	21.3	26.3	24.9	23.5	22.8	15.5	19.1	14.0	15.2	16.8
Pharmaceuticals	9.9	13.4	12.5	11.6	11.2	11.8	14.2	9.8	10.6	10.9
Automotive	10.9	8.5	10.3	10.2	11.6	14.4	12.0	11.1	10.1	9.6
Medical devices	3.3	3.7	3.3	3.3	3.1	1.5	2.4	1.9	1.9	2.1
ICT	6.6	6.9	7.1	6.6	6.3	10.0	12.5	23.5	11.3	12.5
Sum	52.0	58.7	58.2	55.2	55.0	53.2	60.1	60.3	49.1	51.9

Of the reported commodity groups, chemicals goods constitute the largest share for both the EU and Sweden. The commodity group consists largely of pharmaceuticals, which alone represents a share of the same order as automotive. ICT goods are relatively more important for Swedish exports compared with that of the EU. The commodity group represents a share that is larger than both automotive and pharmaceuticals. The table below presents exports from the EU and Sweden to the U.S. as a share of the total exports of each commodity group. The tables thus show the importance of the U.S. as a recipient of exports for each commodity group.

Table 3. Exports to the U.S. from the EU and Sweden
Share of total exports of each commodity (%)

	EU					Sweden				
	2008	2009	2010	2011	2012	2008	2009	2010	2011	2012
Chemicals	26.5	27.2	25.8	24.2	24.1	9.3	9.1	8.7	9.1	9.8
Pharmaceuticals	33.5	33.8	32.4	29.6	29.2	15.6	13.3	12.4	14.2	14.2
Automotive	21.8	20.5	19.5	17.2	19.0	7.9	9.3	8.7	5.9	6.2
Medical devices	34.1	33.0	31.2	30.5	28.0	11.1	12.6	14.1	13.8	14.3
ICT	14.5	15.1	15.6	14.5	15.1	6.2	7.0	14.7	6.5	8.6
Total	18.8	18.5	17.8	16.9	17.3	6.6	6.4	7.3	6.3	6.4

The table above shows that for the EU as a whole, the U.S. is, as a recipient country for exports from these commodity groups, of relatively greater importance in comparison with the importance for Sweden. The U.S. is an important recipient of exports from Sweden with respect to the commodity groups of pharmaceuticals and medical devices. It may be worth noting that the U.S. represents a significantly larger share of the export market for the EU as a whole than for Sweden. This is largely explained by the fact that the Swedish production is part of regional production networks. More information on this is found in the section Global value chains.

6.1.2 Imports

Tables 4 and 5 below present U.S. commodity imports to the EU and Sweden in terms of value and as a share of total imports. The figures thus show the importance of imports of the commodity group from the U.S.

Table 4. Imports from the U.S. to the EU and Sweden
Value (EUR billions)

	EU					Sweden				
	2008	2009	2010	2011	2012	2008	2009	2010	2011	2012
Chemicals	35.7	33.6	38.9	40.5	43.9	0.5	0.7	0.5	0.5	0.7
Pharmaceuticals	14.5	16.4	17.2	19.1	22.0	0.2	0.4	0.2	0.2	0.4
Automotive	8.7	4.5	5.6	6.8	7.9	0.2	0.1	0.2	0.2	0.2
Medical devices	8.6	8.2	8.9	8.8	9.1	0.1	0.1	0.1	0.1	0.1
ICT	23.1	17.3	19.1	19.3	18.9	0.5	0.4	0.5	0.6	0.5
Imports total	182.4	154.9	173.1	191.6	206.1	3.6	3.3	3.6	3.9	4.2

Table 5. Imports from the U.S. to the EU and Sweden
Shares of total imports to the U.S. (%)

	EU					Sweden				
	2008	2009	2010	2011	2012	2008	2009	2010	2011	2012
Chemicals	19.6	21.7	22.5	21.2	21.3	13.4	20.8	13.3	13.1	15.7
Pharmaceuticals	7.9	10.6	9.9	10.0	10.7	6.6	12.8	5.9	6.2	8.4
Automotive	4.8	2.9	3.2	3.6	3.8	6.4	3.8	4.8	4.6	4.1
Medical devices	4.7	5.3	5.1	4.6	4.4	3.2	3.6	3.5	3.2	2.9
ICT	12.7	11.1	11.0	10.1	9.1	13.5	12.3	14.6	14.4	12.2
Sum	49.6	51.7	51.8	49.4	49.4	43.0	53.3	42.2	41.5	43.2

For the EU as well as Sweden, chemicals is the commodity group that constitutes the largest share of imports from the U.S. of the reported commodity groups. For the EU, the commodity groups of chemicals, with the subgroup pharmaceuticals, and medical devises are relatively more important compared with Sweden. Imports of the commodity groups of automotive and ICT are relatively more important for Sweden as compared with the EU. The table below presents imports from the U.S. to the EU and Sweden as a share of the total imports of each commodity group. The tables thus show the importance of the U.S. as a supplier for each commodity group.

Table 6. Imports from the U.S. to the EU and Sweden
Share of total imports of each commodity (%)

	EU					Sweden				
	2008	2009	2010	2011	2012	2008	2009	2010	2011	2012
Chemicals	6.7	7.0	7.0	6.7	7.1	3.8	6.2	3.8	3.6	4.5
Pharmaceuticals	8.9	9.5	9.3	10.2	11.2	8.3	14.3	6.9	7.6	10.0
Automotive	2.3	1.6	1.8	1.9	2.3	2.2	1.8	1.6	1.5	1.5
Medical devises	18.1	18.0	17.2	16.8	16.4	11.3	11.6	11.4	10.6	9.7
ICT	5.5	4.9	4.3	4.4	4.4	3.9	3.7	3.6	3.5	3.4
Total	4.3	4.6	4.3	4.3	4.5	3.2	3.8	3.2	3.1	3.3

Imports from the U.S. are for each commodity group relatively more important for the EU compared with Sweden. Imports from the U.S. to Sweden of both the commodity groups of pharmaceuticals and medical devises constitute 10 percent of the total imports for each commodity group.

6.1.3 Global value chains

The picture of trade was long one of a commodity being manufactured in a factory in one country for export to another country. This picture is now antiquated. Instead, trade is characterised by the production of goods and services divided into stages that are carried out in different parts of the world. This phenomenon has come to be termed “global value chains”. For example, at least one third of Swedish exports now consists of imported goods and services. In many countries, the figure is even higher. The Board has published a number of studies on global value chains that are available on the National Board of Trade website.[83] One of these – *Global Value Chains and the Transatlantic Trade and Investment Partnership* – specifically discusses TTIP.

[83] http://www.kommers.se/verksamhetsomraden/Utrikeshandel/Rapporter-om-handelsutvecklig/.

Traditional trade statistics report all exports from a country as export revenues for that country. This gives an incomplete picture of trade since the import share of the exports is counted in those figures. Furthermore, a large share of exports from Sweden consists of input goods and services. These are goods and services that are further processed in other countries and that in turn often form part of these countries' exports. For example, Germany is a very important trading partner for Sweden, but all exports to Germany do not stay in that country, but are processed further and form part of German exports. Thus, the bilateral trade balances reported according to traditional trade statistics are incomplete. This is due to the import content not being taken into account and to the fact that e.g. the U.S. can import goods and services indirectly from Sweden through a commodity exported from Sweden to Germany perhaps being included in German exports, which in turn end up in the U.S. Of the five sectors requested, there are value-added trade statistics for two, the automotive sector and the chemicals sector. The statistics are taken from the OECD/WTO Trade in Value Added database and are based on trade for the year 2008.

6.1.3.1 **The automotive sector**

One sector that is greatly influenced by the development of global value chains is the automotive sector. In 2008, 48 percent of gross exports from the Swedish automotive sector consisted of imported input products and services. Thus, in fact, almost half of the total export value from the automotive sector in Sweden consisted of imported value. This is value imported in the form of parts and components used in vehicle manufacturing and of services imported to facilitate production. The automotive industry's exports to the U.S. grow in importance when trade is calculated in terms of value added. If both direct exports from the sector and indirect exports are taken into account, the U.S. share increases from 3.2 percent to 5.6 percent of total vehicle exports from Sweden. This means that the U.S. is a relatively more important market for vehicle exports from Sweden when we look at the export value created in Sweden and that has the U.S. as its end market compared with when the sector's import value is included and where only the direct exports from Sweden to the U.S. are reported. For the EU, the relationship is similar. The share of EU exports from the automotive sector that has the U.S. as recipient amounts to 21.7 percent calculated in terms of value added compared with 20 percent calculated according to traditional trade statistics. Thus also for the EU, the U.S. is a more important market for vehicle exports. The greater difference for Sweden than for the EU as a whole is explained by other EU countries, such as Germany and Belgium, importing Swedish input goods and services to their automotive industries and then exporting them in processed form to the U.S. For the EU, this type of input goods and services is counted as internally produced and thus already included in gross trade statistics.

6.1.3.2 **The chemicals sector**

The chemicals sector is another sector that is integrated to a great extent in global value chains. Like the automotive sector, the chemicals sector has a high import content in the Swedish exports from the sector. In 2008, exports from the chemicals sector in Sweden had an import content of 52 percent. The importance of the U.S. for the chemicals sector's exports also grows when trade is calculated in terms of value added. According to traditional trade statistics, the U.S. received 8.2 percent of the chemicals sector's total exports from Sweden. Calculated in terms of value added, the importance of the U.S. increases to 11.5 percent of total exports from the Swedish chemicals sector. For the EU, the U.S. share of the chemicals sector's total exports also increases, from 21.4 percent according to traditional trade statistics to 24.5 percent calculated in terms of value added. Calculations that take into account the import content of exports, as well as both direct and indirect exports, show that

the importance of the U.S. increases for the automotive sector and for the chemicals sector both for both Sweden and the U.S.

6.2 Automotive sector[84]

As a starting point, it is possible to note that the technical characteristics of vehicles in the EU and the U.S. differ. This is due to tax and regulatory differences, but also to cultural preferences, traffic planning and national particularities. This latter, particular national conditions, is one of the main reasons for the lack of a harmonised classification of vehicles, not only between the EU and the U.S. but also globally.[85]

In simplified terms, the most significant differences between EU and U.S. vehicle regulation consist of the markets' use of different requirements and different approval systems for vehicles. As described below in more detail, vehicle conformity in the EU is linked to approval by a national government agency in the EU Member States, while the U.S. uses a system of self-certification. U.S. vehicle regulations consist of federal requirements that often refer to national standards[86], and EU vehicle regulations consist of a mixture of European regulations, international regulations[87] and standards.

6.2.1 Regulatory model

Vehicle requirements internationally are designed partly as technical regulations and partly as standards. With regard to vehicles, there are several different ways to classify requirements. One is that constituted by the *UNECE World Forum for Harmonisation of Vehicle Regulations*, stated in the categories of pollution and energy, general safety provisions, brakes and running gear, lighting and light-signalling, noise and passive safety. The goal of safety provisions is crash avoidance and crashworthiness for vehicles.[88]

Vehicle standards are produced both nationally and internationally. As regards vehicles, the *ISO Technical Committee 22* (TC22) is a central forum.[89] Regarding vehicle classification, the EU and the UN (UNECE WP.29[90]) use a uniform classification of vehicles, at least with respect to type approvals. (The technical regulations themselves, drafted by WP.29 are called "ECE"). However, this is not to say that countries outside the EU need to register their vehicles according to that classification.[91]

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[84] This part deals mainly with the regulation of passenger cars. When rules are compared for other types of vehicle, such as heavy trucks, this is specifically stated.

[85] Deals on Wheels - The Harmonisation of Vehicle Regulations, National Board of Trade 2008:5.

[86] *Federal Motor Vehicle Safety Standards* (FMVSS)

[87] UN regulations (ECE).

[88] A distinction is often made between active and passive safety. Active safety has to do with the prevention of crashes (e.g. requirements on lighting, brakes and tyres), while passive safety aims to minimise the consequences in the event of a crash (requirements on seatbelts, airbags, etc.). As regards energy efficiency, a distinction is made between methods for passenger cars and methods for buses and trucks.

[89] It may be noted that there is a high correlation between ISO standards and the rules developed by the UNECE and the U.S. For more information, see the National Board of Trade study: *Deals on Wheels - The Harmonisation of Vehicle Regulations*, 2008:5.

[90] *UN Economic Commission for Europe* (ECE) and *Working Party 29* (World Forum for Harmonisation of Vehicle Regulations).

[91] Within the EU type approval system vechicles are categorized according to the total weight and the number of passanger seats. Corresponding categories are also used for driving licences. United States lacks the same categorization and it might be problematic to define whether a vehicle is a truck or a

6.2.1.1 **The EU**

Within the EU, the Member States' regulation of vehicles is governed by Directives and Regulations proposed by the Commission and the Directorates-General – DG Enterprise and Industry, DG Trade, DG Mobility and Transport and DG Environment. The statutes are subsequently adopted by the European Parliament and the Council. Implementation of EU law and any national rule applications falls on the agencies of individual Member States. In Sweden, it is the Swedish Transport Agency that is responsible for vehicle issues.

In the EU, technical harmonisation for vehicles is based on Article 114 TFEU and the EU's whole vehicle type approval system (EC WVTA[92]). Under this system, manufacturers may obtain approval for a vehicle type in a Member State if it fulfils the Union's technical requirements, and then market it in the entire EU without the need for additional tests or checks. Registration must be granted on simple presentation, by a certificate of conformity.

A central feature of the European system is that vehicle requirements are linked to agency approval, i.e. that supervision over vehicles is carried out by the EU and the Member States. Type approval is by definition a procedure whereby a Member State certifies that a type of vehicle meets the applicable requirements. This presupposes initial inspection before a type approval can be issued, namely, that the manufacturer has the necessary procedures, etc. for ensuring that production conforms to the approved performance, and has procedures for the observation of changes to applicable requirements and the ability to discharge administrative procedures. In addition, there are subsequent checks of production conformity.

EU vehicle rules are based largely on the horizontal Framework Directive 2007/46/EC[93] (replacing Directive 70/156/EEC), which is directly applicable in the Member States. The Regulation regarding type approval[94] in turn refers to around thirty (26) more detailed Directives for different requirement areas[95], such as safety and noise. These more detailed Directives have become outdated in many areas and give references from the horizontal Regulation to the international ECE regulations[96], which in turn are based on international standards in most of the areas.

The ECE regulations that EU had joined are extensive, but it should be noted that the regulations do not cover all areas regulated within the EU.[97] Examples of areas not covered by ECE regulations include dimensions, weight, plates (= manufacturer's plate or prescribed

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passanger car. A possibility might be to classify a vehicle according the regulations in the EU but still use -the technical regulations based on the regulations and vehicle category in the United States.

[92] European Community Whole Vehicle Type Approval.

[93] 2007/46/EC establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles.

[94] Type approval means that a vehicle, equipment or parts must be tested by an accredited body (which is evaluated by a government agency) for the manufacturer, through a type approval certificate, to be able to place the vehicle on the market.

[95] There are 70 requirement areas, which refer to EU Directives, EU Regulations and ECE regulations. All requirement areas are not applicable to all vehicles.

[96] The UNECE regulations consist of two agreements aimed both at improving traffic safety in the EU and eliminating barriers to trade consisting of varying vehicle provisions in different countries; *Agreement concerning the Adoption of Uniform Conditions of Approval for Motor Vehicle Equipment and Parts* (1958 Agreement) and *Global Technical Regulations for Wheeled Vehicles, Equipment and Parts which can be fitted and be Used on Wheeled Vehicles* (1998 Agreement). The latter made it possible for countries outside the EU to join common vehicle regulations.

[97] Fifty-six UN members are signatories to the agreement, including important trading parties such as Japan, and Russia and most of the world.

markings and space for rear registration plate) and Air Conditioning (AC). There are ECE regulations in the areas of exhaust emissions and noise, in which the EU wants to "take the lead". It is right that contracting parties may themselves determine which regulations they want to adopt, but the EU as a body has acceded to a number of these, which means that EU members cannot opt out of them.[98]

Consistent technical harmonisation has already been achieved in many vehicle categories within the EU, such as light and heavy vehicles and trailers, motorcycles and certain agricultural and forestry tractors. The work of harmonisation will soon also be extended to other vehicle categories, other tractors and trailers and towed equipment.

It is thus possible to argue that the European regulatory framework for vehicles is fully harmonised with respect to *new vehicles* and largely follows international standards. With regard to *vehicles in use*, there are national implementations in different Member States[99], and it is possible to note that there is very little harmonisation for vehicles in use[100]. The EU has requirements for roadworthiness inspection and for certain spare parts, such as brake pads and catalytic converters. However, the basic assumption may be that vehicles that have entered service with the support of a type approval do not generally change (other than being repaired) and thus continue to fulfil harmonised requirements, which means that roadworthiness inspection to detect repair needs is sufficient. Otherwise, the Member States are quite free to set requirements on the nature of vehicles and their equipment. Many countries, including Sweden, have prescribed a requirement level that is largely similar to that resulting from type approval.

Thus, with regard to imports of new passenger cars from the U.S., the EU's type approval system is applied in accordance with Directive 2007/46/EC. It is possible to have a European whole approval or individual approval under 2007/46/EC. As an alternative, a private importer or company may make use of Regulation No 183/2011[101] on the individual approval of vehicles when importing a new or used vehicle that has been registered for a maximum of 6 months. The Regulation is designed to facilitate the import of individual vehicles from third countries. The Regulation may also be applied in the case of commercial imports, and due to costly testing, it is precisely this it is best suited for. The Regulation applies to all

[98] For UNECE 1958, parties that have joined may themselves choose which regulations they wish to adopt. The rules do not contain different levels of requirements, and the agreement entails mutual recognition of type-approval between the parties. The 1998 agreement (to which the U.S. has acceded) differs from the first in that there are differences in requirement levels, which means that the regulations may come to be used differently between different countries. The 1998 agreement also does not entail any mutual approval between the parties.

[99] In Sweden, the following are applicable, for example; the Swedish Transport Agency´s regulations and general guidelines TSFS 2013:63 on cars and trailers towed by cars, and the Swedish Transport Agency's regulations and general guidelines TSFS 2010:02 on cars and trailers towed by cars and are taken into use the 1 July 2010 or later.

[100] A comparison of vehicle imports from the U.S. to the EU and to Sweden shows that imports of used vehicles are more significant for Sweden than for the EU on average. According to statistics from Eurostat, in 2012 the EU (including SE) imported used passenger cars from the U.S. for almost EUR 292 billion, while imports of new passenger cars amounted to nearly EUR 5213 billion. The used share was about 5% and the new share 95%. In 2012, Sweden imported SEK 186 million in used vehicles from the U.S., while imports of new passenger cars amounted to SEK 355 million. The used share was 34% and the new share 66%.

[101] Commission Regulation (EU) No 183/2011 of 22 February 2011 amending Annexes IV and VI to Directive 2007/46/EC of the European Parliament and of the Council establishing a framework for the approval of motor vehicles and their trailers and of systems, components and separate technical units intended for such vehicles (Framework Directive).

third countries, but as it often refers to U.S. (sometimes Japanese) standards, it gives the impression of being particularly intended for U.S. cars. Requirements for air conditioning, if such is fitted, can be very difficult to meet for a car that does not have a "sister model" intended for the European market. Nevertheless, the Regulation is a step on the way towards reducing barriers to trade, but as mentioned only applies to individual vehicles. Typical among the special requirements that still remain between the markets are, for example, the colour of lamps, speedometers according to the European measurement system (km/h) and tyre requirements, where the law requires certain adjustments in the vehicles brought in from the U.S.

Other EU initiatives

Another EU initiative that is worth mentioning in the regulatory context is *Competitive Automotive Regulatory System for the 21st Century* (CARS21). The initiative was based on requests from the European automotive industry for a review of their regulatory framework and led to work with contributions from industry, unions and politicians to strengthen the European automotive industry's competitiveness, increased employment while maintaining safety, environmental consideration and sustainability and vehicle availability. The CARS21 report from 2011[102] contains 18 recommendations and a plan for a European regulatory reform. The proposals include better regulation and review of opportunities for the internationalisation of the European regulatory framework, especially against ECE. The report also notes that European rules are becoming increasingly global as most other countries are adopting the same rules as are used in the EU, but that the issuing of the EU's own rules must always take into account rules outside the EU when new draft regulations are produced. CARS21 has been supplemented by an action plan (CARS2020), which continues along the same lines and where a special group of experts has been established to work with the issues. With this it may be said that the European automotive industry sees itself as global and that competitiveness also increasingly lies in global rules.

6.2.1.2 **The U.S.**

In the U.S., it is Congress that grants broad powers to agencies to create and implement regulations. At the same time, Congress also has the opportunity to steer individual agencies, which in turn are to produce draft regulations with impact and safety analysis. In the automotive field, the relevant agency is the *National Highway Traffic Safety Administration* (NHTSA). Regarding environmental issues, it is the *Environmental Protection Agency* (EPA) that is responsible.[103]

The U.S. uses national standards *Federal Motor Vehicle Safety Standards* (FMVSS).[104] These include 42 standards that vehicles sold in the U.S. must meet. Furthermore, these express minimum requirements on safety performance that must be met by vehicles and vehicle parts and against which they must be certified.[105] It should be noted that a high correlation between American national standards and ISO standards also exists in the U.S.

The U.S. system of vehicle requirements entails self-certification without any agency approval. The self-certification used by the U.S. and also e.g. Canada means that

[102] Wilber and Eichbrecht, *Systematic Implications on Transatlantic Regulatory Cooperation and Competition*, 2011.

[103] Emissions standards are primarily stated in *the Clean Air Act.*

[104] These consist of: Part 571 of Title 49 (Transportation) of the *Code of Federal Regulations* (CFR). In addition, the vehicle must meet the Bumper Standard (49 CFR Part 581) and the Theft Prevention Standard (49 CFR Part 541).

[105] These standards differ between passenger cars and heavy trucks.

manufacturers themselves certify that a vehicle meets technical regulations before it is placed on the market. They do this through a certification mark that proves that the vehicle meets all mandatory safety requirements during manufacture and when the vehicle is placed on the market. Subsequent to this, NHTSA exercises regulation through inspections of vehicles in use and may demand withdrawal or make use of penalties and other sanctions if the vehicle does not meet the requirements.[106] The U.S. is also a signatory to the UNECE agreement of 1998 that provide opportunities to apply the ECE regulations more flexibly (with different requirement levels) and which does not create a mutual recognition of certifications between contracting parties.

What is specific to FMVSS in the U.S. is that the standards differ from the rules in most other countries. Even countries that have not adopted the ECE regulations often have rules that are similar or based on them, which means that the products can be sold in several markets. From an EU perspective, the U.S. rule system means that a vehicle manufactured in accordance with the European regulatory framework cannot be exported to the U.S. Any modifications would also not facilitate market access for European companies as the system shares no common denominator with EU regulations. In the current situation, this means that European vehicle manufacturers have to make market adjustments to their product according to the requirements found in the U.S.

In addition to separate taxes, such as the *Corporate Average Fuel Economy* (CAFE) and the *Gas Guzzler Tax* (GGT), that affect the European automotive industry, the "origin labelling system" based on *The American Automobile Labelling Act* (AALA) can also mentioned. The regulations specify that passenger cars must be labelled with the proportion of vehicle parts which originated from the U.S. and Canada, as well as the origin of engines and gearboxes.[107] The aim is to influence consumers to buy domestic cars and influence car manufacturers in the U.S. to use domestic vehicle parts. As part of the *Made in USA* strategy, AALA has not surprisingly led to complaints from many countries, including the EU and Japan, that the act is discriminatory.

With regard to harmonisation *within* the U.S., it can be said that the federal rules should apply throughout the U.S. However, within states, there may be implementation differences, e.g. with respect to the environment.[108]

Other requirements

As with most sectors, automotive in both the EU and the U.S. is affected by regulation in other areas. Mention may be made to e.g. EU chemicals legislation that requires the tracking of chemical substances on the list of hazardous substances.[109] Manufacturers and suppliers must be able to specify the origin of the substance for each part and component in a car, which thus burdens companies with considerable administrative costs.

[106] Wilber and Eichbrecht: Systematic Implications on Transatlantic Regulatory Cooperation and Competition, 2011.
[107] See, 49 CFR Part 583.
[108] A case in point here is California, which deviates from federal requirements (Swedish Transport Agency, *Interview*, 2013).
[109] *Registration, Evaluation, Authorisation and Restriction of Chemicals* (REACH), Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

With respect to REACH, the Swedish automotive industry is especially critical that:

1. Lead times to remove a substance that is new to the "notification list" are very short. The industry believes that more time is needed, "despite" IMDS[110].

2. Many substances have entered the notification list without having "identity numbers", e.g. CAS numbers. These must be provided for, otherwise the industry does not know what to look for.

3. Primarily for manufacturers of light vehicles, REACH has become legislation that overlaps other legislation. For example, REACH may require a much faster phase-out of lead than the long and carefully planned phase-out of lead deriving from producer responsibility for end-of-life vehicles[111].

Other requirements to mention in addition to the REACH legislation are mandatory recycling (producer responsibility for vehicles, batteries)[112], prohibition of hazardous substances in vehicles (heavy metal ban[113]), rules for biocidal products[114] or social responsibility (conflict minerals[115]).

Other work that should be noted in this context is that conducted by the EU Member States to develop their own tax rules for carbon dioxide emissions.[116] These rules are not harmonised and will no doubt increase fragmentation and possible barriers. The purpose of the measures is to achieve the internationally agreed objective of climate negotiations, to limit the global temperature increase to 2°C. As part of the developed countries' contribution to meet this objective, the EU has also adopted a long-term target to reduce emissions by 80-95 percent by 2050, through domestic measures and measures in countries outside the EU. The EU, unilaterally, has decided to cut greenhouse gas emissions by 2020 by 20 percent compared to 1990 emissions levels, while increasing the share of renewable energy to 20 percent.[117]

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[110] *International Material Data System* (IMDS) is the automotive industry's global database for reporting purposes.

[111] Directive 2000/53/EC.

[112] In Europe, this entails requirements on the recyclability of end-of-life vehicles (2000/53/EC applies to cars up to 3.5 tonnes) and waste batteries (2006/66/EC). The corresponding producer responsibility does not yet exist in the U.S. In the autumn, the UNECE adopted a new requirement for recyclability, based on 2000/53/EC. The only country in the autumn that did not have a stated ambition to adopt this rule was Japan.

[113] The Swedish Transport Agency states, e.g. a ban on lead in the balancing weights in wheels (the latter is permitted so far in the U.S.). See also Directive 2000/53/EC.

[114] Biocidal products are such products as are used to protect people, pets and other property against damage from pests or microorganisms. They are primarily used in industry but also in households. Some examples are antifouling paints for ships, wood preservatives, rodenticides and insecticides. Preservatives, antibacterial agents and disinfectants are also biocides. The Biocidal Products Regulation 2012/528/EC will be applied in the EU from 1 September 2013. It is not yet clear how this will affect the automotive industry, which can be direct or indirect users of biocidal products in raw materials in articles.

[115] The EU has no legislation on conflict minerals, such as the U.S. statute *Dodd Frank 1502.*

[116] In Europe, passenger cars and light trucks are covered by carbon dioxide requirements (see Regulations 443/2009/EC and 510/2011/EU).

[117] Swedish Environmental Protection Agency, *Underlag till en färdplan för ett Sverige utan klimatutsläpp 2050*, Bilagor till rapport 6537, December 2012.

With regard to environmental requirements for vehicles, Swedish stakeholders have varying views on whether the EU's environmental requirements should be regarded as more far-reaching than the environmental rules of the U.S. Indications vary among agencies and between industry actors. However, this mostly relates to the markets' different approaches to achieving environmental goals (diesel/petrol, particles/nitrous oxide, etc.). A concrete example is emissions requirements. The EU applies absolute limit values for each individual vehicle, which may be compared with the U.S. that uses averages for a fleet of cars (different car models). Something that has also emerged is that there are differences in environmental application between U.S. states, while this situation also characterises EU Member States. Other more specific barriers also exist and should be considered e.g. with regard to procurement (*Buy American)*, workplace safety, etc. but is not discussed here in detail.[118]

6.2.1.3 **Comparison**

Thus, in the automotive field, there are differences between the EU and the U.S. both in terms of standards[119] and how compliance with the regulations is checked. It should be noted that the systems are not necessarily completely mutually exclusive – the U.S. uses the type approval method to exercise supervision over emissions standards, and the EU has had unimplemented proposals on self-monitoring as a complement to the type approval system. One exception is the area of emissions, where follow-up checks are performed on in-service cars to verify sustainability requirements.[120]

Despite differences in vehicle regulation in the EU and in the U.S., there is a broad consensus that the level of traffic safety does not differ greatly between the markets and that there is a high degree of functional equivalence between ECE and FMVSS standards.[121] According to the Swedish Transport Agency, the vehicles brought in from the U.S. to the EU also live up to an equivalent level of protection in relation to the requirements of the EU. It is true, however, that there are some areas where the EU has its own particular requirements, especially for tyres, speedometers and the environment, as well as forthcoming regulation for stability systems and automatic emergency braking. A practical example raised by trade and industry is that the EU's safety approach is more integrated than that in the U.S., e.g. for heavy vehicles. The EU has, for example, higher demands on driver safety and preventive safety, meaning that a U.S. truck would not be accepted in the EU. At the same time, the EU largely already follows international regulations that are shared by a great number of other markets.

In an analysis from the U.S. perspective, it is found that the U.S. can utilise a harmonised and largely international regulatory framework within the EU (that is also applied in large parts of other countries) and that the importation of vehicles for private use is facilitated by the alleviations provided in EU law. Export via Germany is especially favourable as special legislation was created for trade with the U.S. during the Second World War.[122] There are

[118] ECORYS, *Non-Tariff Measures in EU-US Trade and Investment – An Economic Analysis*, OJ 2007/S/ 180-219493.

[119] Examples include functional and safety standards (pedestrian protection), approval procedures (recycling, emissions, access to repair information).

[120] Durability checks for in-service vehicles are a voluntary commitment and are thus not mandatory through EU legislation.

[121] Here it may be noted that traffic safety features for heavy trucks are significantly more burdensome in the EU than in the U.S. Even in terms of appearance, there is a great difference between trucks in the EU and the U.S. regarding dimensions and weight.

[122] Germany has developed somewhat favourable procedures for the approval of individual vehicles, which means that it can be attractive to first register a vehicle there.

certain aspirations within the EU for already registered vehicles to be more easily transferred between Member States. However, according to the Swedish Transport Agency, this sometimes creates problems in practice.

For EU manufacturers, there are no alleviations for export to the U.S. A vehicle manufactured according to the EU's type approval system cannot be sold in the U.S. Thus, to gain market access in the U.S, manufacturers in the EU are forced to have a separate production that is completely adapted to U.S. rules. These requirements not only apply to purely technical regulations, but also to different types of charges and taxes.

The fact that the EU works with the ECE regulations, and negotiates free trade agreements with many countries on the basis of the ECE regulations, is seen by some stakeholders as a possible opening for the U.S. to review its regulations in order to avoid competitive disadvantages on the world market. The U.S. regulatory framework has thus far served as protection with respect to its own market. As more countries begin to work with other regulatory frameworks, the current situation could, in other words, be challenged, and make the current U.S. approach competitively inefficient.

6.2.2 Uncertainties/Barriers to trade

A harmonisation of transatlantic rules, that is, the processes that currently regulate vehicle approval (self-certification for vehicles in the U.S. and government agency certification in the EU), is a major challenge. The system used in the EU also unites the EU Member States with third markets, while the U.S. system is national. The question is also whether a change of regulatory framework in the automotive field in the U.S. would at all be feasible.[123] There is much that speaks against harmonisation; a bilateral harmonisation can easily bring about requirements that differ from international requirements and that lead to barriers with third parties. This is also the reason why global initiatives and regulatory cooperation in the automotive sector have hitherto been concentrated under the UN umbrella.

Neither does an MRA on conformity assessment appear to be an option as the regulatory system and the process that a vehicle must undergo to be deemed to conform to requirements are not comparable between the EU and the U.S. There is no foundation in the EU for testing against U.S. rules and vice versa. The principle of reciprocity is, according to the automotive industry's proposal, considered more realistic, provided there is agreement on the issues that divide the markets (dimensions/weight, speedometers, the environment, etc.).

A concrete proposal for a solution put forward by the industry is for U.S. vehicles to be sold on the EU market certified by the national body against the US FMVSS rules. The product will be certified by a government agency according to the EU's type approval process. In the corresponding case of EU vehicles being exported to the U.S., the European product is to meet all the requirements of EU vehicle law equivalent to those in the U.S., as well as any other areas only regulated in the U.S. The product should be certified according to the process applicable in the U.S. (self-certification). In both the above cases, where the same area of legal requirement (e.g. rear-view mirrors) is assessed as non-equivalent in terms of safety, the requirements of the market in which the vehicle will be registered shall apply. Generally, in cases where there are *Global Technical Regulations* (GTR), these should be

[123] Most other surveys and sources support this. Common harmonised rules in the form of *Global Technical Regulations* (GTR) are only achieved in areas where both parties lack regulation or where only one regulation exists in the EU or the U.S. (Wilber and Eichbrecht, *Systematic Implications on Transatlantic Regulatory Cooperation and Competition*, 2011).

implemented coherently into the domestic system and used without additional national legal requirements or options.

As mentioned, other barriers, such as taxes, charges, marking and vehicle classification, constitute problems that exclude and impede market access for the European automotive industry in the U.S. The work on rules between the markets should strive for a positive balance that is sustainable on the basis of a regulative perspective, but that also creates more reciprocity with regard to the gains of regulation. To date, a "two-standards-world" has existed, serving as a base for competition between the markets with the goal of global acceptance for its own regulations. If this competition continues, there are risks of further rule fragmentation in the form of third countries that might begin to apply both frameworks, thus creating new and unique regulatory systems – a development that would benefit neither the EU nor the U.S. The greatest gains should lie in a *one-stop-shop* for testing and certification. However, this would require considerable political will and intensive cooperation between the regulatory agencies.

As for other free trade agreements, such as the new generation of agreements between the EU and South Korea and the EU and Canada[124], the constellations do not lend much support to TTIP. These agreements mainly concern the greater acceptance of ECE regulations by the EU's counterparts – something that perhaps does not reach TTIP's level of ambition.

A long-term goal could be for the approval of motor vehicles and their components manufactured to the technical regulations of one party to be accepted as if they also fulfil the technical regulations of the other party. The initiatives developed by the industry should be able to serve as a starting point for this work. Such a process may be envisaged as taking place gradually and may include concrete timetables for future regulatory convergence work. Here, greater reciprocity should be in focus. The way forward should be based on rule comparison linked to an analysis of the effects of these regulations. If they can be considered equivalent, they should be embraced by mutual recognition. The strengthening of cooperation within the UNECE could reasonably be another goal of the negotiations.

Looking at the current situation, Regulation 2011/183 contains exemptions from the European Framework Directive with the recognition of equivalence of the U.S. FMVSS and *Society of Automotive Engineers* standards (SAE standards), except in a few areas, such as noise. This can be viewed as adaptation rather than mutual recognition as the U.S. does not accept Regulation 2011/183 for imports to the U.S. Regulation 2011/183 can still be considered a rule comparison with some exceptions. In practice, the exemptions mean that the Regulation can only be used for individual vehicles, not entire vehicle types.

One way forward that has been raised is for the negotiations to work on larger clusters of rules, such as those for active/passive safety and the environment. According to the National Board of Trade, this would facilitate opportunities to reach consensus on the overarching issues.

A risk that can be seen in cluster approximation is that it can lead to negotiations on minor details and deviations that can complicate the entire process, especially if the premise is that the EU and the U.S. must successively agree on major, complex areas in order to achieve a successful outcome to the negotiations. The Swedish Transport Agency sees parallels in the GTR process, where it was difficult to move forward and agree on various regulatory areas

[124] For the free trade agreement with Canada, there is a political agreement – the agreement texts are still under development.

with more underlying rules, such as those on brakes. At worst, this can prolong the process, especially if it is supposed that the parties must successively agree on major, complex areas in order to move forward in the negotiations. A cluster approximation might thus be applicable to existing regulations with parties working towards mutual recognition, but would be a more difficult method for new regulations.

It should be noted that there are major differences in how Swedish vehicle manufacturers view the benefits of TTIP. There are actors that have invested billions in fully adapting their production to U.S. regulations and wish to see a status quo. It is true, however, that a greater unity and mutual acceptance of rules could, even for these actors, lead to increased flexibility in the longer term due to greater acceptance facilitating imports and exports of e.g. vehicle components. There are also stakeholders that, at current situation, refrain from exporting to the U.S. referring to regulatory differences between the markets as an important motive. For them, the outcome of the negotiations could be critical to an opening for increased trade. However, work towards common international rules (GTR, WVTA) is something that all stakeholders believe should be promoted as a sustainable model in a global perspective.

The National Board of Trade supports the overall forms of regulatory cooperation that have been proposed, i.e. greater mutual acceptance linked to work towards global vehicle regulations.

6.2.3 Cooperative forms

Regulatory cooperation between the EU and the U.S. has been conducted since 1995/1996 under the *Transatlantic Business Dialogue* (TABD), *Transatlantic Economic Partnership* (TEP), from 1998 in the *High Level Regulatory Forum* (HLRF) and the *Transatlantic Economic Council (*TEC) from 2005 and 2007. For the automotive sector, these dialogues have resulted in the exchange of information and a *Memorandum of Understanding* (MoU) on vehicle safety.[125]

International harmonisation

There have for a long time been attempts to harmonise vehicle regulation internationally, primarily within the UNECE, Working Party 29, and through two existing multilateral agreements in this area from 1958 and 1998.[126] As it has not been possible to adapt these agreements to the globalisation of the automotive industry, new initiatives have been made in GTR with the goal of an international vehicle type approval system that corresponds to the EU system. Here, however, it has only been possible to reach agreement on a smaller number of areas, such as doors/locks. The work has been extremely slow. In addition to pure attempts to achieve harmonisation, the work over the years has accommodated discussions on mutually accepted certification processes, the coordination of impact assessment for new regulations, improved information and the encouragement of the policy to recognise vehicles that meet ECE, EU or U.S. standards.[127]

The coherence between the ECE regulations and the U.S. FMVSS is one of the central starting points of the regulatory proposals now put forward for transatlantic vehicle regulations by trade and industry in the EU and in the U.S. Trade and industry sees great

[125] In automotive, the U.S. has regulatory cooperation with several countries and markets, such as NAFTA, APEC, South Korea and China. EU's free trade agreements with, inter alia, South Korea and Canada, encompass closer regulatory cooperation.
[126] See the National Board of Trade report, *Deals on Wheels - The Harmonisation of Vehicle Regulations*, 2008:5.
[127] Wilber and Eichbrecht, *Systematic Implications on Transatlantic Regulatory Cooperation and Competition*, 2011.

gains in closer regulatory cooperation and that cooperation between the EU and the U.S. could constitute an international model for vehicle regulation. The starting point for the proposal[128] developed by ACEA[129] and the AAPC[130] is the desire for strong political backing, ambitious goals for the negotiations and the desire not to augment the mass of rules with new ones. The starting point is to create unilateral or mutual acceptance of existing rules on the base of rule comparison. The industry starts from a non-exhaustive list of regulations on both safety and the environment.[131] These are to be mutually accepted unless regulators can demonstrate that the legal requirements are deficient from a safety or environmental perspective. In areas where mutual recognition cannot be reached, new technical harmonisation will be proposed. If new rules need to be produced, the initiative will aim to develop common regulations in the GTR process under UNECE WP.29.

Other organisations in the automotive sector[132] have also submitted their requests ahead of TTIP to the EU. These organisations submit requests for the development of global rules in UNECE WP.29. They especially request global labelling of tyres.

The Swedish automotive industry supports the transatlantic proposals drafted by ACEA and the AAPC. The logic behind the proposals is that if equivalent vehicle legislation exists, there should be mutual recognition between EU and U.S. regulators.

As for vehicle importation, the Swedish Association of Vehicle Importers (BIRF) believes that the existing EU framework would give the Swedish regulatory agencies greater opportunities to approve vehicles from the U.S. At present, this is impeded by special national applications that differ from EU practice. The Swedish Transport Agency believes that Sweden does not have any special national applications for vehicle imports, but that Regulation 2011/183 is to be met in full.[133] Furthermore, it should be noted that the Swedish Transport Agency is currently working on regulatory comparisons between the EU and the U.S. in order to facilitate the process of approval of vehicles that only shown to conform US requirments.

With regard to heavy vehicles, the Swedish truck industry views vehicle regulation in the EU and the U.S. in some areas as equivalent regarding the level of safety and emissions, while in other areas there are differences that cannot be considered equivalent. In addition, there are areas of legal requirements where the U.S. has no regulation that corresponds to that of the EU, such as for *Advanced Emergency Braking System (*AEBS) and *Lane Departure Warning* (LDW) and vice versa. For areas where vehicle regulation is deemed equivalent, there should be a mutual approval between the EU and the U.S. But for areas that lack regulation, or where regulation in a particular area is not considered equivalent, the U.S. will meet the EU's requirements for export to Europe and vice versa. For areas with GTR, those GTR will be used instead of national legal requirements. Examples of such areas are engine emissions and *On Board Diagnostics* (OBD) for engines, where GTR 4 and GTR 5 already exist. The vehicle's fulfilment of legal requirements is assessed according to the approval process applicable in the country it will be registered, i.e. certification and type approval by a

[128] AAPC and ACEA, *Joint Submission in Support of Automotive Regulatory Harmonization in a European Union-United States Trade and Investment Agreement,* 7 December 2012.
[129] The European Automobile Manufacturers' Association**.**
[130] American Automotive Policy Council**.**
[131] AAPC-ACEA List of U.S. and EU Comparable Safety Regulations, 1st draft April 15, 2013.
[132] Motor & Equipment Manufacturers Association – US/ European Association of Automotive Suppliers (CLEPA) and EU, US Rubber Manufacturers Association and US and European Tyre & Rubber Manufacturers Association (ETRMA)
[133] Certain other Member States, such as Germany, accept the use of some parts of the Regulation.

government agency in Europe and self-certification in the U.S. At the same time, the whole industry believes that the most important thing is to work towards global rules in the area so as to create a uniform market. It would like to see the U.S. involved in the development of an international WVTA[134].

Vehicles in other free trade agreements
The cooperation agreement between the EU and the U.S. would not be the first to have a special focus on rule simplifications for vehicles. The EU's agreement with South Korea, which entered into force in July 2011, contains a vehicle annex.[135] The central point of the agreement in terms of vehicles is the use of the ECE regulations as the basis of vehicle regulation and the acceptance of vehicles on the market, something that was new, especially for South Korea as a contracting party.[136] It is somewhat early to fully evaluate the outcome of the agreement, but it may be noted that the core of the agreement and its future prospects for a successful implementation primarily lie in increased agency cooperation on regulation issues. The FTA between the EU and Canada (CETA[137]) will also regulate vehicles. That which may be deduced from the objectives here is that Canada will recognise a list of standards used in the EU[138], which are subsequently introduced into Canada's rules[139].

6.3 The information and communications sector (ICT)

Products or goods in the sector of information and communications technology are often "cross-border" and are found in many other sector categories. One example is electronic products that are categorised in another sector, but where many products are affected by the same legislation, barriers to trade and potential solutions as products in the ICT sector.

The definition of goods in the sector of information and communications technology (ICT) has evolved over the years. The *Organisation for Economic Co-operation and Development* (OECD) gives definitions and guiding principles for defining ICT products that are based on the product's functionality.[140] The definition reads "ICT goods must either be intended to fulfil the function of information processing and communication by electronic means, including transmission and display, or use electronic processing to detect, measure and/or record physical phenomena, or to control a physical process". An ICT product can be both a product (a good) and a service according to this definition, which entails a complexity in the analysis of e.g. desired rule changes in the sector.

According to the OECD definition, the main commodity groups consist of: electronic data processing (EDP) equipment; office equipment; control and instrumentation; radio

[134] Whole Vehicle Type-Approval.
[135] Other annexes included in the agreement concern consumer electronics, pharmaceuticals and chemicals.
[136] Prior to concluding the agreement, South Korea used ECE-type rules, FMVSS standards and its own standards as well as a self-certification system besides environmental rules. See also, Perrau De Pinninck, *The EU-South Korea Free Trade Agreement Motor Vehicles and parts Addressing non-tariff barriers and promoting convergence and recognition*, DG Trade, European Commission.
[137] Comprehensive Economic and Trade Agreement.
[138] Seventeen ECE standards and the opportunity to recognise an additional 8 standards within the next 3 years. The texts include a work programme that comprises a study of regulatory coherence with the U.S.
[139] Motor Vehicle Safety Regulations.
[140] OECD 2009 http://www.oecd.org/science/sci-tech/42978297.pdf.

communications (including mobiles) and radar; telecommunications; consumer equipment; and components.

The following analysis of regulation in the ICT sector focuses on industrial ICT products (goods). The National Board of Trade's analysis is thus limited to goods that may be attributed to international provisions in the WTO Agreement on Technical Barriers to Trade (the TBT Agreement). Based on the low number of actors that chose to comment on this sector, the result cannot be considered representative of "Swedish interests". That which the analysis below highlights as the interests of Swedish industry mainly concerns goods that fall under the Directive on radio equipment and telecommunications terminal equipment[141].[142] It should be noted that the Swedish ICT sector is engaged and active in the change process within the framework of international initiatives, such as those of the ITA Committee[143], Orgalime[144] or Digital Europe[145], and documentation from these actors form part of the analysis. Areas such as information security, the internet, services, etc. are not dealt with in the context of this analysis, and thus a large part of the ICT sector falls outside the analysis.

Brief information on the ICT sector in Sweden, the EU and globally

The ICT sector in Sweden is characterised by structural transformation and great dynamics, with many Swedish companies being bought up by overseas groups. It is a fast growing sector and often an important component in the development of many other industries and businesses. The sector is dominated by the service-producing firms.

About a quarter of the employees (about 30 000) in the sector are at companies that produce some form of physical product, "hardware companies", and among these, Ericsson has a very dominant position. Two main categories of physical product manufacturers may be mentioned: manufacturers of computer and electronic components (circuit boards, alarms, monitors, etc.) and manufacturers of complete systems and products (computers and electronics), where Ericsson is the employer of approximately 70 percent of all those employed for that business focus.[146]

The ICT sector in the EU has about 30 percent of the global ICT market. Industrially and technologically, Europe is far ahead with regard to electronic communications, embedded computing, micro- and nanotechnologies and intelligent integrated systems. Europe also has six of the world's ten leading telecom companies and four of the world's ten leading manufacturers of telecom equipment.[147] The sector for radio equipment and telecommunications terminal equipment is one of the few high-tech sectors in which the EU is a world leader, particularly in the area of mobile communications. The products it mainly includes are products that use the radio frequency spectrum (e.g. car door openers, mobile communications equipment like cellular telephones, CB radio, broadcast transmitters) and any equipment connected to public telecommunications networks (e.g. ADSL modems, telephones and telephone switchboards).

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[141] Directive 1999/5/EC.

[142] For example, remote controls, mobile communications equipment, mobile phones.

[143] The Committee for Information Technology Agreement of the WTO.

[144] Orgalime is a European organisation representing the mechanics, electronics and metal industries.

[145] Digital Europe is an organisation that brings together the European digital technology industry and includes large and small companies in information and communications technology and consumer electronics.

[146] Vinnova, *Företag inom informations- och kommunikationsteknik i Sverige 2007-2011*, report number 2013:07.

[147] The Commission, *Public consultation ICT*, 2007, IP/07/988.

The ICT sector is global in nature and its products are found all over the world. One example is that about 75 percent of the world's population has a mobile phone. Electronics and ICT are among the most integrated sectors in the world, partly due to low tariff levels and relatively low levels of regulatory differences.[148] The National Board of Trade's experience is that global companies in the ICT sector are working for change in global forums and would like to see sectoral agreements that include as many countries as possible, e.g. *Information Technology Agreement* (ITA) within the WTO framework.

6.3.1 Regulatory model

Barriers to trade (NTBs) in ICT are described in detail in a major report from 2009.[149] Two sectors in the report may be attributed to the ICT sector. The first relates to electronic products, where a large portion of these can be classified as ICT products and whose legislation is broadly the same. The second sector is office, information and communications equipment. The conclusions drawn in the study are that current barriers to trade are primarily linked to differences in terms of requirements on product standards, testing and certification, consumer protection and the environment, and that there are relatively low levels of regulatory differences. According to the study, harmonisation of standards and mutual recognition of testing and certification represent the most appropriate measures to reduce current barriers in the sectors.

Cooperation has been initiated in the area between actors mainly at the global level, but also between the EU and the U.S. This cooperation is intended both to increase understanding of the system for conformity assessment and to enhance opportunities with regard to testing in accordance with the current system. The area has a mutual recognition agreement (MRA).

6.3.1.1 **The EU**

The central legislation is the Directive on radio equipment and telecommunications terminal equipment[150], the Low Voltage Directive[151] and the Electromagnetic Compatibility Directive[152]. All these Directives fall within the scope of the New Approach and do not contain detailed technical requirements for products, but refer to “essential requirements”, such as those for health and safety. The technical requirements are established in harmonised standards. The use of standards is voluntary, but conformity with the requirements of legislation may be established through application of the harmonised standards (where about 75 percent of the standards are identical to international standards in the sector). That is, when there are harmonised standards for all essential requirements and the manufacturer applies these standards, self-declaration may be used. It is the obligation of the manufacturer to prove that the products are compatible with legislation and to keep the technical documentation available to the agencies.

In order to certify conformity with the Directives, the manufacturer shall produce the technical documentation, issue an EC Declaration of Conformity (hereafter referred to as

[148] ECORYS (2009), *Non-tariff Measures in EU-US Trade and Investment – An Economic Analysis*.
[149] ECORYS (2009), *Non-tariff Measures in EU-US Trade and Investment – An Economic Analysis*.
[150] R&TTE (1999/5/EC).
[151] LVD (2006/95/EC).
[152] EMC (2004/108/EC).

self-declaration[153]) and affix the CE marking. If this is done, the product can then circulate freely within the EU.

Important horizontal legislation that may be perceived as a barrier to companies generally include EU environmental legislation, such as the Ecodesign Directive (energy), RoHS (hazardous substances), WEEE (waste) and REACH (chemicals). This legislation places great demands on companies both within and outside the EU to meet the requirements, even if the Ecodesign Directive and RoHS contain approval procedures that rely on the manufacturer's own declaration of product compliance.

Within the EU, DG Enterprise and Industry is responsible for the R&TTE Directive. Each Member State has a competent authority designated for the area; in Sweden this is the *Swedish Post and Telecom Authority* (PTS).

Possible changes to EU legislation

Some adjustments are underway regarding the legal framework for ICT. According to the PTS, the scope and the essential requirements of legislation may partly change with regard to the R&TTE Directive in its area of application (e.g. fixed terminals will fall outside, radio-broadcasting and television apparatus will be covered). There is a possibility for the Commission to introduce a registration system for certain categories of radio equipment. One Swedish industry representative believes that any changes made to enhance the traceability of products, such as requiring registration systems, are something companies think might cause problems. The PTS and Swedish industry have expressed that the changes might "block" legislation to future changes, which may make it more difficult to adapt or make adjustments in the context of trade negotiations with the U.S. Adjustments or changes made in the context of the TTIP negotiations would require a new proposal and negotiations at the EU level (ordinary legislative procedure).

Standards

The European standardisation body in the field is the *European Telecommunications Standards Institute* (ETSI), whose international counterpart is the *International Telecommunications Union* (ITU); the *International Electrotechnical Commission* (IEC) and the *International Standardisation Organisation* (ISO) are also important bodies. Work often takes place at the various levels with established work programmes (the EU's programme runs 2010-2013). *The European standardisation organisations* (ESO) focus on different industries, but as the ICT area is often inter-sectoral, the work is coordinated by ETSI together with the two other organisations, CEN and CENELEC.[154]

The standardisation process in the EU is considered very flexible; new areas of work can continuously be initiated by members, and standards are then adopted after a vote among members. European ETSI standards immediately apply as Swedish standards. Sweden has *Information Technology Standardisation* (ITS), but it does not represent Sweden internationally in the ITU. Sweden is represented by the PTS.[155] Swedish ITS emphasises that ETSI's standards are developed for a global market and are free and open to all. The U.S. and Europe conduct an operational partnership "with respect to uniform requirements

[153] An EC Declaration of Conformity must always be produced by manufacturers if they themselves certify conformity (self-declaration or manufacturer's declaration are the most common expressions) or if the manufacturer must engage a notified body.
[154] www.etsi.org.
[155] Swedish Government Communication, *The importance of standardisation in a globalised world*, 2007/08:140.

on accessibility", and "accessibility" is a very important field of ICT in the U.S.[156] ITS believes that international standards in this sector have made telecommunications the most interoperable technology ever.

The ETSI standards (relating to certain parts of the R&TTE Directive) are free of charge, which is a major difference compared with other areas in which the standards usually cost money. For example, standards issued by CENELEC on other parts of the R&TTE Directive must be purchased. Standards used for regulation are also adopted as European standard (after a vote among national bodies).

6.3.1.2 **The U.S.**

The central legislation for the sector is regulated in the U.S. by the *Federal Communications Commission* (FCC), which regulates interstate and international communications by television, cable, satellite and radio in all fifty U.S. states. As an independent body overseen by Congress, the FCC is the country's central agency for communications legislation and technological innovation.[157] Hence, as the FCC works with radio frequencies and the products covered by the EU's R&TTE Directive, it is the U.S. equivalent to the PTS[158]. The legislation is contained in the FCC's rules and regulations, Title 47 of the *Code of Federal Regulations* (CFR), which are published and available online in a searchable format. Most FCC rules are adopted through a process whereby the general public is informed of new legislation and has the opportunity to comment on the rules before they can be adopted. Under the FCC is the *Wireless Telecommunications Bureau* (WTB), which develops and implements guidelines and procedures for the licensing of all wireless services, from fixed microwave links to amateur radio for mobile broadband services.

The FCC's Title 47 regulations, an "R&TTE law" as it were, have 199 parts relating to the FCC. Products with active radio transmitters (ICT products) require a certification by the FCC. The requirements apply to products per frequency range. There are three types of process for approving products (depending on risk); verification (resembles self-declaration), approval procedure (declaration of conformity) and certification. *Telecommunications Certification Bodies* (TCB) approve and certify products and also perform market surveillance.

Standards

As mentioned earlier, the U.S. system of standards is market-driven and highly decentralised.[159] The system is divided into sectors, in which independent and private standardising organisations (SDO)[160] operate. *The American National Standards Institute* (ANSI) coordinates the development of *American National Standards* (ANS) through the accreditation of standardising organisations that develop and publish ANS. ANSI is an active member of ISO and the *International Electrotechnical Commission* (IEC). The ICT area includes, for example, *The Telecommunications Act of 1996*, which contains several provisions that call the *Federal Communications Commission* (FCC) to rely on private-sector standards.[161]

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[156] E-mail from the ITS on 2013-09-17. See also, *US-EC Information and Communications Technology Standards Dialogue*, first meeting March 2004.
[157] See the FCC website: www.fcc.gov.
[158] The Swedish Post and Telecom Authority.
[159] See the above section, *Legislative starting points between the EU and the U.S.*
[160] Standards Development Organizations.
[161] See, High Level Regulatory Cooperation Forum Report, 15 October 2008.

6.3.1.2 **Comparison**

The Swedish company that commented on the legislation in the EU and the U.S. points out that, in principle, EU and U.S. legislation has similar requirements "on paper" but that U.S. legislation, the FCC regulations, is in practice perceived as much more complicated than that of the EU. U.S. legislation stipulates requirements for products per frequency range, whereas the EU has requirements related to the product. Trade and industry believes that this poses a greater difficulty in gaining an overview of legislation and of what applies per product in the U.S.

In terms of new products and new technology, one Swedish company points out that the U.S. process can be very slow with delayed lead times of up to eight weeks for product approval. This is due to the centralised system, where the *Telecommunications Certification Bodies* (TCB) cannot approve new technology in the radio area, but must turn to the FCC for approval. In the EU, there are notified bodies in each country, which themselves may approve products to see if they meet the essential requirements of legislation, even products with new technology. In the EU, self-declaration generally applies for most products in the sector, while the U.S. has higher demands than that of self-declaration (self-declaration plus testing in an accredited laboratory, TCB) for products with any form of radio transmitter.

6.3.2 Uncertainties/Barriers to trade

The following describes the main areas of uncertainty, barriers, etc. in the sector. Solutions are also proposed. These descriptions are based largely on interviews with Swedish trade and industry and on documentation from European industry and government agencies.

Procedures for conformity assessment

A general problem for the ICT sector is that the EU and the U.S. have different conformity assessment procedures. This also applies to the electronics sector, to which many ICT products belong. Third-party certification for electronic products (such as low-risk telecom products) that is regulated by the *Occupational Safety and Health Administration* (OSHA) is adopted by companies also with respect to ICT products. Especially in the area of radio equipment, there are differences that directly affect the company for every product that comes on the market. The FCC has certification requirements, including other technical requirements, compared with the EU's R&TTE Directive, which has self-declarations. Provided that both parties have agreed on an equivalent level of protection, the key question to ask, according to one company, is that of "which critical elements should be included in order to be able to agree on mutual recognition".

For radio equipment, a way forward is to perform a detailed review of the certification procedures since many actors highlight this in particular. Orgalime raises the differences between the EU and the U.S. regarding certification structure as a problem. The American Chamber of Commerce advocates a broad agreement for mutual recognition. The German industry association VDMA speaks of OSHA and the certification system in general as problematic.[162] Some basic principles that should govern conformity assessment procedures are stated by industry representatives; the system must be based on trust in the company and that responsibility rests on the company, as well as a simple and transparent system based on market surveillance. The ITA Committee's *Guidelines for EMC/EMI Conformity Assessment Procedures*[163] are referred to as a way forward in the work towards more common rules. The PTS underlines that "self-declaration is a central part of the New Approach legislation. It would be unfortunate to negotiate away this possibility".

Standards

The standards used for ICT products do not constitute a significant barrier to trade as about 75 percent of the standards used are based on international standards. In general, the same basic standards are used, which is a success story in the sector, says one Swedish company. These standards have a very important role in the sector, but there is an ambiguous picture of how they work and what should be done. One Swedish company believes that it should be sufficient for the ICT product page to have a list of commonly accepted standards in the EU and in the U.S. to avoid uncertainties.

A different view is presented by Digital Europe, which points out that standards in the ICT sector have not generally been a problem, but still may come to constitute a barrier to trade between the EU and the U.S. as the systems are very different from each other. Among other things, it is stated that future work should be based on common principles developed by the EU and the U.S. in 2011, as well on the new EU framework for standards that is in place.[164] According to representatives from Swedish industry, mandatory industry standards, that is, "voluntary" standards that are recognised and required by U.S. agencies, without these being published/distributed by themselves or via their websites, can constitute a barrier to trade. This makes it difficult for companies to live up to the standards in the U.S.

The Commission notes in line with previous studies that it is extremely important to work so that standards do not constitute a barrier to trade because there is a lack of harmonisation between the EU and the U.S., for example, regarding the internet or M2M (machine to machine) communication.[165] What can be predicted here is some kind of framework for cooperation and referral in accordance with the TBT Agreement that international standards should be used. The American Chamber of Commerce advocates a broad agreement for mutual recognition with the use of "high" standards. It also wants to see cooperation between CEN/CENELEC and ANSI. Orgalime highlights national mandatory U.S. standards, especially in the electronics field, as a challenge.[166]

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[162] The Commission, *Comments Submitted by the Industry on Regulatory Cooperation Under a Possible EU US Agreement*, 10 September 2012.
[163] See www.wto.org, document G/IT/W/12/Rev.2, and for a preliminary list of different countries' procedures for conformity assessment, document G/IT/W/17/Rev.11.
[164] *Building Bridges Between the U.S. and the EU Standard Systems*, available on the following website: http://www.whitehouse.gov/sites/default/files/omb/oira/irc/us-eu-standards-bridges.pdf. Also note that there is a specific cooperation on ICT standards between the EU and the U.S. for the area accessibility.
[165] ECORYS (2009), *Non-tariff Measures in EU-US Trade and Investment – An Economic Analysis*.
[166] The Commission's compilation, *Comments submitted by the industry on regulatory cooperation under a possible EU US agreement*, 2012.

An example of a barrier to trade raised by one Swedish company, and by Digital Europe[167], is the requirement of "Hearing Aid Compatibility" on all products with active transmitters[168]. In brief, this entails an adaptation of products to the U.S. market because the products are not allowed to interfere with other equipment, primarily hearing aids. Digital Europe emphasises that a way forward for the work on accessibility issues is through international standards and mutual recognition of approval procedures such as self-declaration.

Transparency

The lack of transparency in the area is seen as a significant barrier to trade within the EU and in the U.S. One Swedish actor advocates a cooperative body for the sector with working groups, where product- and service-bound discussions are separated. It is important to work with timetables and performance reports in areas that may be possible to resolve, and to separate product- and service-bound discussions. A platform for mutual exchange between regulatory actors on both sides would therefore be regarded desirable. A concrete solution for rule transparency may be to compile regulatory requirements for trade strategic products and to make these available to actors, e.g. on a web page (with a lot of space given to approval procedures), for example by means of a table as shown below. This has been done with regard to ITA members' conformity assessment procedures for products with electromagnetic compatibility (EMC)[169] and is proposed by one Swedish company also for safety, radio requirements, the environment, etc.[170]

Table example: Regulatory requirements

Product	Approval procedure	Labelling, traceability, etc.	Link to legislation

A general opinion on transparency in the ICT area is a lack of understanding and knowledge of each other's regulatory frameworks. One company speaks of U.S. colleagues not understanding how things function in the EU, e.g. regarding environmental regulations, and thus experiencing the regulatory framework as intricate.

Labelling of products

It is currently required that products with radio equipment and telecommunications terminal equipment must be CE marked in the EU and FCC marked in the U.S. The labelling requirements is a general problem that entails costs for companies and is difficult to administer. For example, there might be a requirement for the physical address of the company responsible to be stated on products (the address leading to the person responsible for the product). In the future, the industry would like to see a simplification of labelling requirements and that the marking may be affixed to the protective film and electronically inside products that have built-in displays (e.g. mobile phones). This is currently permitted in Australia and Japan, for example. The industry believes that this solution allows a continuous updating of the marking, better design and lower costs. It says that it could be valuable to start working on this in the context of TTIP.

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[167] Digital Europe, *Digital Europe position paper on the EU-US regulatory cooperation*, version 2, November 2013.

[168] One company says that this is a big problem as half the products placed on the market must comply with the requirements, which entail a special antenna solution and a different handset.

[169] See, www.wto.org, document G/IT/W/17.

[170] Döfnäs, Ericsson, Informal discussion document, *Furthering global trade in ICT products*, 2013.

Safety issues

In the U.S., the regulations of the *Occupational Safety and Health Administration* (OSHA) are experienced as very burdensome. In this connection, several companies raise the electrical safety area as problematic in the U.S., with various burdensome procedures for approval and checks. The EU has self-declaration for products with low risk, while the U.S. has some form of third-party control even for low-risk products. Swedish industry finds inspections of production facilities burdensome. Most actors believe that third-party certification is acceptable, if only "we are spared the inspections". The OSHA regulations seem extremely difficult to change, the industry believes, and to try to do so might disrupt the entire TTIP negotiation process. But there are perhaps elements of the OSHA rules that could be negotiated, and a way forward might be to survey the regulatory framework in order to analyse potential changes. With regard to the area of electrical safety, which has a great impact on ICT products, self-declaration for low-risk products could be a solution, but the industry raises a note of caution in that the regulations on the U.S. side (OSHA) have little potential for change.

Environmental legislation

The environment is another area that is more regulated in the EU compared with the U.S., for example, in REACH[171], the Ecodesign Directive or in the Directive on electronic waste. The U.S. has in principle no environmental legislation in the area corresponding to that of the EU. Within the EU, both REACH and RoHS have a fundamental impact on product design in the electronics sector (the product side of ICT), such as six substances that are banned in the EU but not in the U.S. It is possible that the number of banned substances will increase in the EU. In the environmental area, several companies say that the requirements imposed by the EU are not particularly controversial; on the contrary, some say they are desirable. However, there is a desire for international harmonisation in the area, where differences in legislation entail great costs for companies.

Market surveillance

One Swedish actor would like to see cooperation on market surveillance for certain products in the EMC and radio area. Another company stresses that simplified approval systems in the ICT sector must include market surveillance to ensure compliance and the attaining of fair competition.[172] One problem highlighted is that market surveillance in the U.S. is partly managed by certification bodies and not the state. Information from the PTS states that there is currently international exchange of experience between the members of the R&TTE Directive's "ADCO"[173] and the FCC. They meet about once a year and mostly discuss specific products. There are no types of joint market surveillance campaigns because the legislation differs.

Regulatory structure of the wholesale market

There is a deficiency in the regulatory structure of the wholesale market for ICT products in the U.S., including a dominant position for two major companies in the market and entry difficulties. U.S. companies appear to find it comparatively easier to enter to the regulated EU market.

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[171] Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), see Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006.

[172] Döfnäs, Ericsson, Informal discussion document, *Furthering global trade in ICT products*, 2013.

[173] Each New Approach Directive has an "ADCO", i.e. the informal group of the national administrations in charge of the market surveillance for this Directive. The ADCO group supports and complements the work of the formal committee or the working party of the Directive.

6.3.3 Cooperative forms

Global initiatives are very important to how the sector has evolved and will evolve in the future. The industry believes that the negotiations between the EU and the U.S. can have a positive effect on global developments and establish a number of guiding principles for trade in the ICT sector. The industry generally believes that TTIP can give momentum to global regulatory developments, such as providing good conditions for the development of global data flows and the mutual recognition of regulation in areas including standards, conformity assessment, marking and the environment, i.e. not only bilaterally. Below are the main cooperative forms that can provide a basis for the work of TTIP.

Good regulatory practice – GRP in the ICT area

An interesting non-paper summarises very briefly how good regulatory practice in this area should be designed.[174] The paper notes that the innovative, global nature of ICT products requires a global regulatory environment using internationally approved standards. Most ICT products are low-risk products, but this is not always reflected in legislation. It should therefore be possible to review the requirements and the procedures for conformity assessment in the sector. It is also crucial that the products quickly come on the market due to short innovation cycles. It is therefore very important for there to be consultations on, e.g. new draft legislation, at an early stage and for approval procedures to be adapted to product risk and to be performed smoothly, e.g. via the internet.

Information Technology Agreement (ITA)

The ICT sector with its global, communicative and innovative character has led to the conclusion of a global ITA agreement. In 1996, the WTO decided on negotiations to eliminate tariffs on information technology products. Following plurilateral negotiations, the *Information Technology Agreement* (ITA) was concluded in 1997. The agreement means exemption from customs duties for IT products, such as computers, semiconductors and telecommunications equipment. The number of member countries has gradually increased, and 97 percent of world trade in the products concerned are now included in the agreement.[175] In pace with the rapid technological advances, the agreement has become antiquated, as many of today's IT products fall outside the agreement and are therefore not exempt from customs duties. Therefore, a revision is hopefully forthcoming. The Commission has stated that goods not covered by the ITA will in some way be treated under TTIP.[176]

Some proposed solutions for the regulation of ICT products that have been raised in the context of barriers to trade in *Non-Agricultural Market Access* (NAMA) under the ITA Committee are also relevant to the negotiations between the EU and the U.S. The Commission has submitted some proposed solutions.[177] This has also been done by a Swedish company, stating that some solutions can be applied to the TTIP negotiations. In its non-paper, the Commission proposes firstly increased transparency by means of a web portal for IT regulation, e.g. on requirements for conformity assessment. The second proposal is to invite those working on legislation in the area within each Member State, and also industry, to exchange experience, culminating in “benchmarks” for GRP in ICT. Guidelines for the digital marking of IT products are also mentioned. The Swedish company says that it is probably the case that the EU/U.S. negotiations will pave the way and boost the work of the

[174] The Commission, Non-paper, *Ideas for an updated approach on NTB in the ITA review*, Expert Meeting April 2013.
[175] See the National Board of Trade website: http://www.kommers.se/Handelspolitiskt-ABC.
[176] The Commission, Civil Society Dialogue, 16 July 2013.
[177] The Commission, Non-paper, *Ideas for an updated approach on NTB in the ITA review*, Expert Meeting April 2013.

ITA Committee and not the other way round. It believes that the number of goods that fall within the agreement must first be expanded before progress can be made regarding non-tariff barriers. A prerequisite for this work is for the EU and the U.S. to have a somewhat common understanding of the issues to be solved, and for this reason, a formal platform for cooperation under TTIP would boost the work.

Mutual Recognition Agreement (MRA)

Since 1998, the ICT sector has had a *Mutual Recognition Agreement* (MRA), which includes mutual recognition of telecommunications equipment and electromagnetic compatibility (and electrical safety).[178]

NIST and the FCC are responsible in the U.S. for approving bodies/companies to perform conformity assessment under the MRA. In Sweden, it is Swedac that is responsible for this. In Sweden, conformity assessment is performed by two companies/bodies. According to the PTS and Swedac, the MRA in the area does not always function particularly well. One larger company uses established bodies in the U.S. to make the certification process as smooth as possible, and it does not use the MRA between the EU and the U.S. Another company gives MRA the nickname "My Regulation Applies". This is meant in the sense that even though the two parties have decided on the mutual recognition of approval procedures, one of the parties (the U.S.) creates additional requirements in its application. If the products have some form of radio transmitter, which is true of many products in the ICT sector, then the MRA adds no real value on account of the additional requirements. For other types of product, there probably is added value for this MRA, which also seems to be confirmed in that the two companies in Sweden that perform conformity assessment do so in accordance with this MRA.[179]

Despite the problems of this MRA, it is still an important cooperation at a deeper regulatory level to work for and accumulate experience of the recognition of conformity assessment procedures, as well as the results of this.

Cooperation within the UNECE

Swedish industry believes that initiatives developed within the *United Nations Economic Commission for Europe, Working Party* (UNECE WP.6) could be used in the negotiations. That which has been developed includes common regulatory objectives for ICT products and for standards, e.g. a list of standards in the EU and the U.S. …Where applicable, the recommendations from the "Telecom Initiative" within WP.6 could be used as a neutral "best practice guidance" for the regulatory work on goods in the ICT area.[180]

Trading principles in the ICT sector

In 2011, the EU and the U.S. agreed on a number of trading principles for the ICT services sector.[181] These concern transparency, networks, use of the spectrum, regulatory and agency issues, etc. The result of developing these trading principles is unclear, but as stated by the Commission, constitutes a basis for work towards greater coherence in the sector, particularly on the services side. This should also be able to apply to the products side, for example regarding transparency and agency structure.[182]

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[178] For a detailed description of the MRA, see the section *Regulatory tools for managing TBT and in-depth analysis.*

[179] Swedac, Statement, Ref no 2013/3692, 20 December 2013.

[180] See http://www.unece.org/trade/wp6/SectoralInitiatives/Telecom/Telecom.html.

[181] EU-US Trade principles for Information and Communication Technology Services, 2011.

[182] The Commission, *Civil Society Dialogue EU*, 16 July 2013, see http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151656.pdf.

Free trade agreements between the EU and South Korea and Singapore
It may be interesting to note whether there is anything specific regarding the ICT sector in other recently negotiated free trade agreements.

The FTA concluded between the EU and South Korea (2011) contains some sections of this kind. Firstly, there are separate sections relating to services and electronic commerce, with subsections relating to data and telecommunications services. Secondly, in the electronics sector, there is also an agreement to enhance regulatory cooperation. This includes a reference to accepted international standards and the mutual approval of certain products through self-declaration rather than third-party certification.[183]

The FTA with Singapore (2013) also contains a special section relating to electronic products, setting out guidelines for cooperation on standardisation and conformity assessment procedures.[184] The agreement also addresses electronic commerce.

Future areas of cooperation
One Swedish company says that in the areas of the environment, conflict minerals and nanomaterials, for example, it is important to already now lay a foundation for more harmonised regulations in the future. However, nanomaterials are also mentioned at the European level. British Telecom also identifies nanotechnology, for example, as a key area for future regulatory cooperation.[185] It is, for example, important to focus on harmonising requirements, such as those for registers or the tracking of products. This area is important not only in the context of the transatlantic negotiations but also at the global level.

With regard to conflict minerals (which many ICT products may contain), the EU and the U.S. have different rule systems containing different products and geographical areas, but new legislation in the field is under development. Here, harmonisation could be applied to disclosure requirements as repeated processes are very costly and should be avoided.

"Software defined radio" is an area for future cooperation in ICT. "Software defined radio" refers to hardware that is delivered with a certain type of software, but a new piece of software changes the technology and function of the product. How these types of product should be handled is under discussion in the EU. One actor says that this area would be valuable to investigate in terms of the approximation of legislation between the EU and the U.S.

The National Board of Trade's assessment and Swedish interests and priorities
The analysis of the ICT sector has focused on industrial ICT products. Areas such as information security, the internet, services, etc. are not dealt with, and thus a large part of the ICT sector falls outside the analysis. The industry representatives that the Board has been in contact with in Sweden express roughly the same positions as those of the European interest organisations, but also largely those of the Commission. It has been difficult to identify Swedish interests that differ from the EU level.

The main barriers to trade that have been highlighted are questions of transparency, conformity assessment procedures and standardisation issues in general. Other major challenges in the sector are horizontal, such as regulation of electrical safety and the

[183] See, http://trade.ec.europa.eu/doclib/docs/2011/october/tradoc_148303.pdf.
[184] EU-Singapore Free Trade Agreement, Annex 4-A.
[185] The Commission, *Comments Submitted by the Industry on Regulatory Cooperation Under a Possible EU US Agreement*, 10 September 2012.

environment. There are relatively low levels of regulatory differences in the legislation. In reality, however, companies perceive the differences as relatively great in some areas, such as conformity assessment procedures and electrical safety (OSHA). There is an MRA between the EU and the U.S. which is relevant to the sector, but which does not function fully satisfactorily in terms of conformity assessment procedures.

Industry believes that future areas for regulatory cooperation that should be included within the scope of TTIP are, e.g. the environment, conflict minerals and nanomaterials. Government agencies and industry have expressed some concern about future adjustments in terms of the legal framework of ICT in the EU.

Mutual recognition of testing and certification or harmonisation of standards appear to be the most appropriate measures to reduce current barriers in the sectors. One solution for increased transparency might be to compile agency requirements and make them available in an easily accessible way. Despite the challenges, the MRA mentioned is still important for cooperation at a deeper regulatory level to work for and accumulate experience of the recognition of conformity assessment procedures, as well as the results of this. This is something that future cooperation should be able to take advantage of. A cooperation body between the EU and the U.S. is advocated by both the Commission and industry in the sector. This body would, for example, be able to perform detailed work on standards or study conformity assessment procedures.

The innovative, global nature of ICT products requires a global regulatory environment using internationally approved rules and standards. The industry believes that the negotiations between the EU and the U.S. can have a positive effect on global developments and establish a number of guiding principles for trade in the ICT sector. The cooperative forms that might constitute a basis for the work under TTIP include international initiatives, such as the work of the ITA Committee or the UNECE, where regulatory objectives and various transparency initiatives for the sector have been developed, e.g. a list of approval procedures for strategically important products.

6.4 Chemicals sector

Chemicals regulation in the EU and the U.S. differs in fundamentally important areas. The EU's chemicals regulation, mainly represented by the REACH Regulation[186], presupposes that it is the producers of chemicals that are responsible for producing the necessary information on the chemicals, submitting it to the *European Chemicals Agency* (ECHA) in order to then introduce it on the market. In the U.S., producers are also to submit information to the competent authority, the *Environmental Protection Agency* (EPA), but they do not need to produce any data other than that they already have available. It is only if the EPA can prove that the chemical poses an *unreasonable risk* that it can be removed from the market.

A report from the OECD shows that a harmonisation, through the OECD's *Environment, Health and Safety Programme* (EHS), of the testing and evaluation of new chemicals and pesticides could reduce costs by up to 153 million EUR per year.[187]

[186] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.
[187] OECD, *Cutting costs in Chemicals Management – How OECD helps governments and industry.* See http://www.oecd.org/env/ehs/47813784.pdf.

In the following text, adelimitation has been made in relation to cosmetics, product safety, waste, water and air quality, areas which are adjacent to that of chemicals and which to a great extent are affected by chemicals legislation.

6.4.1 Regulatory model

6.4.1.1 **The EU**

As early as 1967 the Directive 67/548/EEC[188] was adopted on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. Environmental and health concerns gradually came to play a more significant role, and in 1979, Directive 67/548/EEC was amended so that its purpose also embraced protection of the environment. A distinction between new and existing substances was introduced. The market release of new substances in quantities of one tonne or more required a registration application, to be supplemented by the results of certain tests. The greater the volume to be placed on the market, the more extensive the testing requirements. The tens of thousands of substances that already existed in the market, and were not classified as new, were not subject to the testing requirements. They could circulate freely in the market, provided that they were included on a special list. The relationship between how new and old substances were covered by testing requirements constituted an environmental and health problem as there was a lack of data for a great number of chemicals. This also led to the industry retaining old chemicals instead of developing alternatives.[189]

The current chemicals legislation in the EU largely consists of the aforementioned REACH Regulation. The aim of REACH is to i) ensure a high level of protection of human health and the environment, ii) promote the free circulation of substances on the internal market and iii) enhance competitiveness and innovation. REACH marked a clear shift of focus in that the Regulation was founded on the precautionary principle. The precautionary principle is stated in Article 191(2) TFEU[190]. Article 1(3) of REACH establishes the following:

> "This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle."

The precautionary principle aims to prevent potential risks. The principle is to be applied when there is a potential risk, but where it is not possible to fully demonstrate or quantify sufficient scientific facts or determine its effects. The measures that can be taken in accordance with the precautionary principle need not be in the form of statutes or prohibitions. They may involve informing the public about a product or funding a research project, as shown by the Commission's communication on the precautionary principle.[191] The Commission's communication also states that if it is considered necessary to take measures in order to counteract a risk, the measures must be proportionate and non-discriminatory in relation to the desired level of protection.

[188] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.
[189] Langlet, Mahmoudi, *EU:s miljörätt*, 2011.
[190] The Treaty on the Functioning of the European Union.
[191] Communication from the Commission on the precautionary principle, COM(2000) 1 final.

The basis of REACH is “no data, no market”, as established in Article 5 of the Regulation. This means that substances and mixtures must be registered in accordance with the Regulation in order to be manufactured or placed on the market. There is a limitation to the registration requirement, which means that it is only when at least 1 tonne/year of a substance or mixture is manufactured or imported that a registration application must be made. The information requirement in the registration increases in relation to the increase in volume of the manufactured or imported substance. The information to be submitted in connection with registration is dependent on the volume that the individual registrant manufactures or places on the market. Common to all registrations is that they are to contain information on:

- the manufacture and use(s) of the substance.
- the classification and labelling of the substance.
- guidance on safe use.
- In addition, all available physicochemical, toxicological and ecotoxicological information shall be submitted.

ECHA and the member states co-operate closely on evaluation issues. With REACH, certain chemicals may also be made subject to authorisation.[192] Authorisation is required to be permitted to use substances of the highest concern or for placing such substances on the market. For that type of substance, there are no volume requirements – the authorisation requirement thus applies regardless of the quantity of the substance. A substance may also have a restriction when there is an unacceptable risk to human health or the environment, arising from its manufacture, use or placing on the market.[193] Under Article 20(2) of REACH, ECHA may reject the registration if complete information is not submitted to the agency.

There is an ongoing discussion within the Union on REACH's harmonising effect, where a number of Member States have stated that REACH does not constitute a barrier to national restrictions. This view is not shared by the Commission. *The Swedish Chemicals Agency* (KemI) has investigated whether the ECJ in its ruling on the *Lapin case* (C-358/11) influences the interpretation that Sweden, among others, have made regarding the scope for national restrictions in relation to REACH. KemI interprets the Court's ruling as being in line with the Swedish interpretation – namely that Member States have a smaller scope for national regulation under REACH in comparison with what previously applied under the Limitations Directive.[194] The work on notifications of technical regulations includes the current consolidation of Directive 98/34, where the Commission has developed a new version. The consolidated version contains wording, parts of which clarify the manner in which restrictions on chemicals are to be made. According to the National Board of Trade, it may be assumed that a number of Member States may have opinions on this that are not in line with that of the Commission.

Under Articles 75, 117 and 138, REACH was to be reviewed five years after entering into force. This review was undertaken In 2012, resulting in a report from the Commission. The results of the review have been interpreted by the Commission to mean that REACH is

[192] Substance evaluations are carried out by a designated member state. See http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation.
[193] Annex XVII of the REACH Regulation.
[194] Swedish Chemicals Agency memorandum, *Lapin-målet (C-358/11) – Reachförordningens harmoniserande verkan*, dnr 13-335.

functioning well and is achieving the objectives that may be assessed at present. No amendments to the Regulation itself are proposed. What the Commission would like to change is how the provisions affect the costs of small and medium-sized enterprises (SMEs). In an annex to the report, the Commission submits a number of recommendations for how to achieve this. For example, a main objective of the revised Fee Regulation is to lower the costs for SMEs. The annex further states that improved guidance will be produced regarding the protection of intellectual properties in the context of mandatory exchange of information as well as more user-focused guidance for SMEs. At a public consultation in autumn 2012, REACH was identified by SMEs as one of the 10 most burdensome pieces of EU legislation.[195]

Private and civil stakeholders

During the review, the industry was invited to submit improvement proposals. One European industry association commented that the chemicals industry has made significant investments to comply with REACH and felt that REACH should not be changed at this time, but be kept as it is in order to provide stability and opportunities for the industry to accumulate experience of current regulations. Other comments received concerned the hope that the EU will work for international solutions with respect to regulation in this area. The forthcoming regulation of nanomaterials is highlighted as an example of areas where dialogue is requested between the EU and the U.S. on how the regulatory framework should be designed. It was further stated that chemicals regulation should primarily take place through REACH and not through the national regulation of individual Member States. Integrated regulation by means of REACH increases uniformity and the opportunity for the industry to work towards a predictable regulatory framework. However, this presupposes that ECHA works transparently and communicates plans for forthcoming regulation.

Consumer organisations have raised concerns about how a future free trade agreement between the EU and the U.S. could result in less protection for consumers if this entails the easing of regulations.

6.4.1.2 **The U.S.**

There are a number of different laws regulating the manufacture and sale of chemicals. However, the leading one is the *Toxic Substances Control Act* (TSCA) from 1976, according to which the *Environmental Protection Agency* (EPA) is the competent authority.[196] The original purpose of TSCA was to shift the burden of proof regarding a chemical's safety to the company that produces it. Under TSCA, the EPA, in cases where it believes the substance may constitute an unreasonable risk, is permitted to require that a substance be tested for health and environmental effects if the substance is produced, imported or processed in the U.S. When new chemicals, or existing chemicals considered to be in a "significant new use", are to start to be produced or imported, the company shall submit a *premanufacture notification* (PMN). This is to include data on:

- the substance's composition.
- planned production levels.
- planned use.
- and available health and safety information.

[195] The European Commission, *General Report on REACH*, COM(2013) 49 final

[196] For more information visit, http://www2.epa.gov/lawsregulations/summary-toxic-substances-control-act.

There is no requirement for companies to produce new data for the sole purpose of filing a PMN. This information is thus missing in many PMNs, and the EPA instead has to rely on its knowledge of similar substances in order to evaluate the risks of the new substance. The EPA has the power to restrict or prohibit a substance if it constitutes an unreasonable risk to human health or the environment. The EPA can only do this where it is able to prove that it is the least restrictive measure. This is something that has been interpreted narrowly by the courts.[197] Criticism has been levelled against the EPA in this context because the agency has only decided on restrictions for five existing chemicals.[198]

Some states, including California, Maine and Massachusetts, have gone further and introduced a more restrictive chemicals regulation than that established in TSCA. For example, California's *Safe Drinking Water and Toxic Enforcement Act* (Proposition 65), stipulates information requirements similar to those of REACH, and the proposition applies to chemicals on California's counterpart to the candidate list. There is nothing in TSCA to prevent states from adopting rules concerning chemicals.[199]

In 2009, the EPA's assessment and control work relating to the enforcement of TSCA, was put on the U.S. Government Accountability Office's list of areas that are at high risk for waste, fraud, abuse and mismanagement. A number of different proposals for revisions to TSCA has been proposed since then, but none has yet been adopted.[200] Now, another attempt at revision of U.S. chemicals legislation is in progress, and proposals have been presented from different sources on what new regulation should contain. One proposal for new legislation that has won support from Democrats, Republicans and various industry associations is the *Chemical Safety Improvement Act* (CSIA). CSIA means, among other things:

- that all chemicals used for commercial purposes are to be assessed.
- that the EPA should focus on those chemicals that require the greatest vigilance.
- that it will become simpler to require manufacturers to conduct additional testing when necessary; the requirement that EPA must prove unreasonable risk will be removed.
- that it will clarify when federal rules are above state rules.
- that it will stipulate which information submitted by manufacturers to the EPA may be published.[201]

Private and civil stakeholders

The American Chemistry Council believes that TSCA is an antiquated regulatory framework that lacks the confidence of those who have to apply it and also among the population. They are demanding a more transparent and effective tool in the EPA's work to assess chemicals and have proposed a system to prioritise chemicals on the basis of i) risks to human health, ii) environmental impact, iii) the use and volume of the chemical, iv) whether it is taken up

[197] European Parliament, DG for Internal Policies, *Legal Implications of the EU-US Trade and Investment Partnership (TTIP) for the Acquis Communautaire and the ENVI Relevant Sectors that Could be Addressed During Negotiations*, 2013.
[198] Bergkamp, *The European Union REACH Regulation for Chemicals*, 2013.
[199] Bergkamp, *The European Union REACH Regulation for Chemicals*, 2013.
[200] Bergkamp, *The European Union REACH Regulation for Chemicals*, 2013.
[201] See, http://reformtsca.com/Main/CSIA-Fact-Sheet.pdf.

in people's bodies and the environment, v) whether they are in products for children and vi) the extent to which there are reliable data and studies on the chemical.[202]

The National Electrical Manufacturers Association, however, believes that TSCA is a sufficient tool for the EPA and does not want to see any change in the U.S. system, in particular any approximation towards REACH.[203]

6.4.1.3 **Global**

Globally Harmonised System of Classification and Labelling of Chemicals

Within the framework of UNECE activities, a system has been developed called the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS). The assessment of a chemical's physical properties and dangers to health and the environment is made on the basis of globally agreed criteria. The purpose of the GHS is to contribute to increased chemicals safety and to facilitate trade in chemical products and substances. In addition to the criteria for classifying substances, the GHS also contains rules on the design of packaging labelling and safety data sheets.[204] The GHS was adopted in December 2002, and the latest revision came in 2013. The GHS is not binding, but all member states have been encouraged to introduce it before the year 2008.[205] The EU has adapted its legislation to the GHS through the CLP Regulation[206]. The U.S. has only adapted its work environment legislation to the GHS.

Mutual Acceptance of Data (MAD)

The OECD's chemicals programme currently has a system, the Mutual Acceptance of Data (MAD), to which all OECD countries and several non-members belong. In working with chemicals, testing is a resource-intensive factor, with the same chemical frequently being tested and assessed in several countries. To facilitate this, the OECD adopted a decision[207] in 1981 to the effect that data produced in one member country in accordance with the OECD's *Test Guidelines* and *Principles of Good Laboratory Practice* (GLP) shall be accepted in other member countries. Data on health and environmental risks that have been produced in one member country in accordance with these principles and guidelines shall be accepted by the competent authorities of other member countries in their assessment work. Data should therefore not need to be produced a second time in order to assess the risks of the chemical. In 1989, a further decision[208] was adopted to guarantee that the production of data is in accordance with the principles of GLP. It establishes procedures to verify that the work is in compliance with GLP, inter alia, through agency supervision and a framework of close cooperation between the agencies of member countries.

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[202] American Chemistry Council, http://www.americanchemistry.com/Policy/Chemical-Safety/TSCA/ACC-Proposes-New-Prioritization-Tool-to-Increase-Effectiveness-of-EPAs-Chemical-Review-Process.pdf.

[203] National Electrical Manufacturers Association, http://www.nema.org/Policy/Environmental-Stewardship/Documents/NEMA%20REACH%20TSCA%20White%20Paper%20052107.pdf.

[204] Swedish Chemicals Agency http://www.kemi.se/sv/Innehall/Lagar-och-andra-regler/Klassificering-markning-och-sakerhetsdatablad/GHS/.

[205] UNECE, http://www.unece.org/trans/danger/publi/ghs/histback_e.html.

[206] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, Preamble, Recitals 5-8

[207] Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals.

[208] Recommendation of the Council on Compliance with Principles of Good Laboratory Practice.

REACH from a global perspective

According to information from both the industry and the Swedish Chemicals Agency, the legislation of some countries is undergoing an approximation towards REACH. The clearest example appears to be South Korea, whose legislation is called K-REACH and contains rules with a corresponding registration procedure, encouragement to use green chemicals and parties coming together to produce data. The regulation has also shifted from a focus based on *hazard* to one based on *risk.* The use and manufacture of chemicals will be reported to the environment ministry, substances and chemicals must be registered, and a list of priority substances will also be produced.[209] The change came after it was noted that the differences between South Korea's own legislation and that of the EU and the OECD countries were damaging to the nation's chemicals industry.[210] On 1 July 2011, the free trade agreement between the EU and South Korea entered into force. The agreement has four sectoral annexes on electronics, motor vehicles and motor parts, pharmaceuticals/medical devices and chemicals. The annexes contain specific commitments from the parties that are of considerable practical relevance.[211] What significance the EU-Korea FTA has had for the development of K-REACH is difficult to say; however, an initial proposal for K-REACH was presented in the first half of 2011.

India has also amended its legislation and proposed REACH-like legislation, though not as far-reaching.[212] In conjunction with China's adoption of new chemicals legislation in 2010, the Environmental Defence Fund commented that China had thus overtaken the U.S. by adopting legislation corresponding to that which the domestic industry had warned of, since it had argued that this type of legislation would lead to production being moved to China.[213]

6.4.1.4 **Comparison**

Division of responsibilities

The two systems differ fundamentally in terms of the division of responsibilities for chemicals and the risks they entail. In the EU, REACH places responsibility on manufacturers. If they cannot present data for the chemicals they want to manufacture or handle, they may not enter the market. If there is evidence that there is a risk, albeit scientifically uncertain, a preventive measure can be justified in light of the precautionary principle. In the U.S., the division of responsibility is the opposite. In order to restrict chemicals, it is the responsibility of the EPA to present data that demonstrates an unreasonable risk. Until this can be done, the chemical is free to be placed on the market. In order to require further information from companies, the EPA must demonstrate the existence of an unreasonable risk. Therefore, the EPA must itself generate data if companies are not willing to share the data they hold. The EPA's discretion in terms of restrictions has also been interpreted narrowly by the courts, which has hardly strengthened the EPA's position.

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[209] Bergkamp, *The European Union REACH Regulation for Chemicals*, 2013.
[210] Chemical Watch, http://chemicalwatch.com/14975/k-reach-becomes-law.
[211] The European Commission, DG Trade, *The EU-Korea Free Trade Agreement in practice*, http://trade.ec.europa.eu/doclib/docs/2011/october/tradoc_148303.pdf
[212] Chemical Watch, http://chemicalwatch.com/16614/india-considering-legislation-that-would-be-simpler-than-REACH.
[213] Chemsec, http://www.chemsec.org/news/news-2010/october-december/649-new-chemicals-regulation-in-china

Within the EU, both new and existing chemicals are regulated through REACH, while TSCA only regulates chemicals that are new on the market. When TSCA was introduced in 1976, there were already 62 000 chemicals on the market for which data was therefore not required.[214]

The principles of protection

The EU's regulatory framework assumes that data can be presented to describe a chemical's impact on human health and the environment. The same is not true in the U.S., where the EPA can request information, but cannot require manufacturers to produce it. The quantity of data and information currently reported to the various agencies is different in scope. The mandates of the competent authorities differ. Thus, in principle, the EPA may only request information, while ECHA can require the information it needs, and if the information is not produced, market access is withheld.

Opportunities for restrictions

The REACH framework contains use restrictions for approximately 100 chemicals, for a group of chemicals that constitute a risk for safety and environment as well as authorisation requirements for an increasing number of dangerous chemicals. Since TSCA was adopted in 1976, restrictions have been decided for five chemicals.

Accessibility of information

Relevant in the context of U.S. information criteria is *Confidential Business Information* (CBI). Under the provisions of TSCA, companies can require information they have submitted to the EPA to be treated as CBI and thus not be made public. Under TSCA Section 8(e), a company that manufactures, uses or distributes a chemical, and obtains information that it presents a substantial risk to health or the environment, must notify the EPA of this. Reports under Section 8(e) are made available on the EPA website. However, in cases where a company has demanded that a chemical be kept confidential, the name of the chemical is redacted in the public report.[215]

REACH requires companies that are to register a substance in REACH to form a *Substance Information Exchange Forum* (SIEF) to share information, especially test data. The purpose of this requirement is to keep down the number of animal studies when producing new information on the hazardous properties of the substance. How this is to be done is something the legislator has left for companies to manage. In practice, it has usually been managed by means of companies having formed consortia whereby registrants of the same substance have come together and through legally binding agreements regulated the allocation of data ownership and costs between the parties. Trade and industry representatives have often spoken of this has having been very complicated to work out, with major and costly input from lawyers.

KemI has noted that REACH and ECHA have gone a long way in making public the information that is submitted to ECHA in the registration dossiers. The information that can be found on the ECHA website is more detailed than the corresponding information on the EPA website. Large amounts of compiled information are thus available via the ECHA website, while the consortium owns the raw data and other information not used in the registration dossier. In the first two registration rounds for higher volumes (tonnes/year/company) in 2010 and 2013, the registrants were primarily larger companies

[214] Vogel, Swinnen, *Transatlantic regulatory cooperation*, 2011.
[215] EPA, *Increasing transparency in TSCA*, http://www.epa.gov/oppt/existingchemicals/pubs/transparency.html#cbi.

that had formed consortiums. KemI also notes that ahead of the last registration round with the lowest volumes, it will be predominantly SMEs that are registrants, mostly for substances that are already registered. These then have two options in principle: to pay for all testing themselves or to buy into an existing consortium. One of the most important issues for ECHA, the Commission and the Member States at present is how best to support SMEs so that they are able to comply with REACH requirements. In order to reduce the burden, SMEs have, by the regulation that stipulates fees, got a strongly reduced fee for self-registration. One of the greatest remaining concerns is the cost related to the access and generation of test data.

The relation of other countries to REACH
As other major countries approximate their legislation to REACH, the U.S. might fall behind if it does not follow the trend. From an innovation perspective, the U.S. may lose ground by not renewing its chemicals legislation. Lower requirements do not offer the same incentive to develop alternative, less harmful chemicals.

The fact that different countries develop national legislation that in various ways are similar to REACH will enable the regulatory framework for chemicals to become more uniform. However, it might mean that the regulations will differ on key points for the industry, e.g. concerning how test data is to be produced and requirements that the tests be conducted at designated laboratories.

6.4.2 Uncertainties/Barriers to trade

From what is stated above, the National Board of Trade notes that there are a number of uncertainties to elucidate, such as the division of responsibilities, which differs in some fundamental respects, how information will be shared between the parties and the fact that the U.S. is currently revising its legislation.

Division of responsibilities
The regulations are based on entirely different principles, such as with respect to who is responsible for the chemicals that are placed, and are already present, on the market; similarly, at what stage checks should take place and which data needs to be presented. The division of responsibilities is thus fundamentally different.

Accessibility of information
One of the greatest difficulties for SMEs in being able to comply with the REACH rules is the costs of buying into consortia and gaining access to the information required to submit their registration. For many SMEs, the option of paying for new tests themselves, or in a new consortium, is an unreasonable one. It is important to point out in this context that after 2018, no substances (besides a few exceptions) that have not been registered will be allowed on the European market, in accordance with one of the foundational principles of REACH, “no data, no market”. KemI believes that it is difficult to see consortia volunteering information, which they own and in which they have made substantial investments, to companies or government agencies in the U.S. and which has not been submitted to ECHA and published on its website.

Innovation
The European industry has invested in its production in order to adapt it to REACH and, in light of these investments, has an advantage over U.S. industry with respect to a shift towards a more regulated chemicals industry. It offers opportunities for European companies to launch new, more sustainable solutions to those consumers who are demanding these.

Swedish industry has also adapted to the current regulatory framework and has invested heavily in research and innovation.

Revision of TSCA
The fact that TSCA is currently being revised in the U.S. can be seen as a factor of uncertainty depending on which direction the new regulations are developed. This opens the way for industry associations to influence both the TTIP negotiations and the design of national regulations. It gives the EU an opportunity to influence the new U.S. regulations and to contribute experiences and conclusions from REACH.

Agreement text and cooperative form
In order to describe the cooperation in the area of chemicals, it is very important to look at the terms used in a forthcoming agreement. At what level will the cooperation take place? If cooperation is expressed in terms of consultations in connection with the drafting of new rules, there is a risk that this will prolong the legislative process and thereby inhibit developments towards safer chemicals. Sweden has been a driving force in raising, e.g. endocrine disruptors, on the European agenda, and we are very keen to continue driving chemicals legislation forwards towards the safe use of chemicals.[216]

As mentioned above, there is an ongoing discussion on the opportunities for Member States to adopt national restrictions in the area of chemicals. Sweden's position in these discussions has been that this possibility exists and has in part justified this by saying that it is necessary in order to quickly remedy the risks of hazardous chemicals, and that it moves developments forward as some Member States have made more progress in the context of working with chemicals.

GHS
The U.S. has not implemented the GHS, other than in its work environment legislation. A crucial question is thus the extent to which the U.S. is willing to implement the GHS criteria in other areas, such as industrial chemicals and plant protection products.

6.4.3 Cooperative forms

The prioritisation of chemicals for analysis, approximation in classification and chemicals labelling, cooperation on new areas and increased information exchange and protection of trade secrets, are likely to be core areas of regulatory cooperation on chemicals in the negotiations.

Neither the EU, the U.S. nor the industry have expressed aspirations for a harmonised chemicals legislation in the context of TTIP. The reasons for this vary, but the conclusion is still the same. It appears instead expedient to work to achieve the lowest levels of regulatory cooperation, i.e. information exchange/rule transparency and the observation of overarching international commitments. As regards, e.g. the development of test data, the ambition could be to achieve common procedures and acceptance of this data without any requirement for new testing, e.g. through MAD. Hence, a first step might be to promote greater transparency in relation to existing regulations so that the parties gain better knowledge of each other's regulatory frameworks and the processes these involve (including US State level). ECHA and the EPA have previously signed a cooperation agreement to the effect that the agencies

[216] The Commission has expressed that EU will keep its regulatory autonomy and will withhold its general approach towards the chemical legislation.

already share information to some extent.[217] The cooperation could be deepened and intensified through a partnership agreement.

The Swedish Chemicals Agency has expressed concerns that TTIP might lead to a weakening of chemicals regulation, that it might hinder rule development regarding, e.g. endocrine disruptors, that the process of developing new regulation will be inhibited by, e.g. lengthy consultation procedures between the parties. At the same time, it has, like the Commission, raised the classification and labelling of substances as an area for cooperation, as well as information exchange, provided that it is an information exchange with no obligations, for example, to await approval from the other party or to refrain from investigating substances because they are being investigated by the other party. Thus, there is a consensus about what may be possible and appropriate to cooperate on, albeit with slightly different starting points for how the areas are to be handled.

The exchange of information can be seen at different levels: i) information that aims to increase knowledge between the different parties and the transparency of existing regulations, ii) information that aims to provide the respective agencies with data held by the counterpart and iii) information with which producers must provide the agencies when they wish to manufacture or place chemicals on their market.

At the national hearing held by the National Board of Trade in December, there were views that work forms can be developed for achieving greater information exchange without any party needing to give up its regulations. A forthcoming agreement could accommodate an agreement on transparency and approximation in future legislation. The industry has expressed concerns about what the increased exchange of information would entail, wishing to safeguard the protection of trade secrets and to ensure that investments made to meet REACH requirements have not been in vain. Besides this, it advocates transparency between the different regulatory frameworks, such as the recognition of test data in order to avoid the unnecessary costs of further testing. It also emphasises that harmonisation of the regulatory frameworks is not seen as desirable at present.

Full implementation of the GHS by the U.S. would open the possibility of common minimum criteria. The same principles for classification and labelling would make it easier for the industry. This would probably also simplify the exchange of information between competent authorities. As the criteria may also be shared with many other parties, it could benefit global trade and make it easier for companies that are in a number of different markets.

KemI sees an opportunity to develop joint work on prioritisation, risk assessment and the assessment of substances at the technical level. KemI emphasises, however, that it is important that this be done without commitments in a regulatory context as the U.S. is far behind Europe and would thus hinder continued European development. The opportunity to perform reconciliations between the various parties' assessment programmes can be raised without, however, getting caught up in wording that prevents the assessment of a substance under REACH because the corresponding substance is being assessed in the U.S. It is pointed out that the most important factor is transparency, i.e. that the information is available to both parties without binding them to a specific procedure.

[217] Statement of Intent on chemical management activities. See http://www.epa.gov/oppt/echa.epa.soi.pdf.

6.4.3.1 **Conclusions**

The two systems differ fundamentally in terms of the division of responsibilities for chemicals and the risks they entail. In the EU, REACH places responsibility on manufacturers. If they cannot present data for the chemicals they want to manufacture or handle, they may not enter the market. If there is evidence that there is a risk, albeit scientifically uncertain, a preventive measure can be justified in light of the precautionary principle. In the U.S., the division of responsibility is the opposite. In order to restrict chemicals, it is the responsibility of the EPA to present data that demonstrates an unreasonable risk in order to be able to restrict chemicals. Until this can be done, the chemical is free to be placed on the market. In order to require further information from companies, the EPA must demonstrate the existence of an unreasonable risk. Therefore, the EPA must itself generate data if companies are not willing to share the data they hold.

Neither the EU, the U.S. nor the industry are seeking a harmonised chemicals legislation, and to promote this would therefore appear unnecessary. It appears instead expedient to work to achieve the lowest levels of regulatory cooperation, i.e. information exchange/rule transparency and the observation of overarching international commitments. There are in some cases already established systems on which to build, such the GHS for the classification and labelling of chemicals and MAD for the production and exchange of data.

Concerns have been expressed that TTIP might lead to a weakening of chemicals regulation, that it might hinder rule development regarding, e.g. endocrine disruptors, that the process of developing new regulation will be inhibited by, e.g. lengthy consultation procedures between the parties. Cooperation should mainly focus on increased cooperation without regulatory commitments. It is important that the further process highlights the wording presented and investigates the actual meaning of the cooperative form, e.g. a consultation procedure in conjunction with the drafting of new rules.

The industry has expressed concerns regarding data exchange as well as the desire for continued acceptance of its ownership of the data it has produced. This is a significant aspect to illuminate. Nevertheless, it is important to keep in mind that this view is not necessarily shared by SMEs, which have far weaker opportunities to generate data.

It may be noted that other countries have approximated their legislation to REACH. If the U.S. were to do the same, they would have access to an even larger market. The risk for U.S. companies is otherwise that their market will decrease to the advantage of other actors from Europe or Asia that have adapted to more restrictive regulations. If their products may be placed on the most regulated market, they can be placed on any market at all.

6.5 Pharmaceuticals sector

The pharmaceuticals sector is generally characterised by being production heavy, with extensive costs for research in the development of new drugs as well as a relatively heavy regulatory burden. In addition to research-based pharmaceutical companies, there is a group of companies which trade in generic drugs and do not have the same character of developing activities as the research-based companies. This group is instead governed by various market procedures in order to gain access to different markets. Also important to note is that there is a global trend towards moving the manufacture of pharmaceuticals to third countries, while retaining innovation and research.

The pharmaceuticals sector is subject to a relatively extensive international cooperation, and there are harmonisation processes in various constellations. There are thus certain structural similarities at the international level. The pharmaceuticals market is in many respects a global market, and many pharmaceutical companies currently operate across national borders. This means that the pharmaceuticals sector operates on a global plane in terms of both regulation and market, opening the way for new and progressive forms of cooperation. The EU and the U.S. signed an agreement on mutual recognition in 1997. This agreement, however, was a failure and is now ineffective. Therefore, cooperation between the EU and the U.S. in the pharmaceuticals sector has the potential to improve.

6.5.1 Regulatory model

Generally speaking, pharmaceuticals in the EU and the U.S. are regulated with the aim of ensuring medical safety and efficacy. An appropriate way to describe the regulatory framework for pharmaceuticals based on this main purpose is to trace the pharmacetuical route between different regulatory bodies; from development, application for authorisation, marketing authorisation, to safety monitoring after a medicine has been authorised (pharmacovigilance). Most of the content of pharmaceuticals regulations concern these processes. In addition to this, there are safety-related requirements that drugs must meet in order to be sold as well as formal and administrative procedures to ensure that applicable safety levels are met satisfactorily.

Representatives of the public sector, government agencies and supervisory bodies, have a strong judicial position in the pharmaceuticals sector. The prominent role of agencies means that cooperation between agencies is a key area for achieving effective processes and regulatory coherence (applies especially to the EU). Furthermore, pharmaceuticals are to a high degree subject to regulations on intellectual property protection. Extensive drug development costs and the agencies' needs for large amounts of data to ensure drug safety and efficacy mean that there is a strong need for the industry to protect its investments.

6.5.1.1 **The EU**

State influence and agency structure

Within the EU, the Member States have exclusive competence over their healthcare systems. In addition to healthcare, Member States have powers to manage the purchasing and pricing of pharmaceuticals. This means that the pharmaceuticals sector is both affected by a largely harmonised EU law for drugs (in particular substantive requirements for authorisation) and relatively extensive national powers to manage national healthcare systems. For drugs, this means that Member States have their own pharmaceuticals authorities (in Sweden, the Medical Products Agency), which are responsible to ensure that the drugs available on the national market are safe and efficacious.

Alongside the national pharmaceuticals authorities, there is also an EU agency that manages pharmaceutical issues, the *European Medicines Agency* (EMA). The EMA manages marketing authorisation for drugs at the EU level and has the task of coordinating the scientific evaluation of the safety, efficacy and quality of drugs undergoing a certain marketing authorisation procedure for new drugs (described below). EMA does also handle some scientific questions that might arise in the market authorisation process. The EMA works so that only one authorisation consideration has to be necessary for a drug to have access to the EU internal market. The EMA also performs monitoring, coordinates supervision and if necessary can withdraw authorisations for medicines authorised under the

centralised procedure (see below). The exercise of authority in the area of pharmaceuticals is thus divided between both EU agencies and national agencies.

Substantive requirements and procedures for marketing authorisation

A large part of the regulatory framework for pharmaceuticals is harmonised within the EU. This includes requirements on the manufacture of pharmaceuticals, requirements on clinical trials, procedures for marketing authorisation and rules for the monitoring of products after they have been authorised. There are also provisions in related areas, such as the wholesale distribution and advertising of medicines. In addition, there is harmonised legislation concerning certain types of drugs, such as medicines for rare diseases and medicines for children.

In the manufacture and importation of drugs, harmonised legislation imposes requirements on the drug's being manufactured according to "Good Manufacturing Practice" (GMP). Manufacturers and importers must be able to demonstrate that the drug has been manufactured according to the principles and guidelines of GMP.[218] In order to ensure that drugs are safe, harmonised legislation imposes requirements on clinical trials.[219] In other words, a medicine must have been tested before it can be authorised. These trials make it possible to predict and identify the drug's effect on humans. Following completed clinical trials, companies can apply for authorisation to sell the drug in the EU internal market.

Within the EU, drugs can be authorised for sale in three ways: the centralised procedure, the mutual recognition/decentralised procedure and the national procedure. The *centralised procedure*[220] means that applications are processed by the European Medicines Agency (EMA) and leads to the granting of a European marketing authorisation by the Commission that is binding in all Member States. This procedure is mandatory for certain types of drugs.[221] The *mutual recognition procedure*[222]/*decentralised procedure*[223] applies to products that have been authorised nationally. The procedure is based on the principle of mutual recognition and means that products that have received authorisation at the national level shall in principle receive authorisation in other Member States on the basis of the first authorisation. According to the same principle as with mutual recognition, the decentralised procedure is based on a first authorisation in one Member State. The difference is that the procedure applies to products that have not yet received a marketing authorisation at the time of application. The procedure allows several applications to be processed at the same time, while the substantive assessment is only made in one country. Until 1995, the *national procedure* was the system that was used in the authorisation of new drugs. Until 1998, there was still the possibility in some cases to use this national authorisation system although the

[218] Directive 2001/83/EC, Directive 2001/20/EC, Directive 2001/82/EC. The Commission has also developed GMP guidelines through Commission Directive 2003/94/EC and Commission Directive 91/412/EC.

[219] Directive 2001/20/EC. The Commission has developed guidelines for clinical trials through Commission Directive 2005/28/EC. This also establishes guidelines on *Good Clinical Practice* (GCP).

[220] Regulation (EC) No 726/2004.

[221] Products derived from biotechnology, orphan medicinal products and medicinal products for human use that contain an active substance authorised in the EU since 20 May 2004 and that are intended for the treatment of AIDS, cancer, neurodegenerative diseases or diabetes. The centralised procedure is also mandatory for medicinal products for veterinary use that are intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals.

[222] Directive 2001/83/EC.

[223] Directive 2004/27/EC.

product had been approved in another Member Sate. This possibility now only remains for such medicines as are only sold in one member country.[224]

When a drug has been authorised in the EU and has been placed on the market, the drug is monitored throughout its lifecycle. This monitoring is called *pharmacovigilance* and is designed to monitor the drug's benefit-risk balance in order to ensure that the benefit always outweighs the risk when used.[225] If such a risk arises, the product's marketing authorisation can be withdrawn. In 2012, the pharmacovigilance regulations were updated in the EU.[226] The changes meant, among other things, improvements to the quality of safety data sheets, greater transparency, clearer division of responsibilities between market authorisation holders, national agencies and the EMA, enhanced EU decision-making procedures and the establishment of a Scientific Committee at the EMA.

Direct imports, parallel imports and parallel distribution

Trade in medicinal products can in principle be done in several ways in the EU; direct imports, parallel imports and parallel distribution. *Direct imports* occur when the same company that has introduced a drug on one national market chooses to sell (import) the drug to another Member State. *Parallel imports* refer to the trade in medicinal products that occurs as a result of differences in drug prices making it profitable for companies to buy up cheap products in one Member State, repackage and sell them in the market of another Member State at a higher price. *Parallel distribution* is in principle the same procedure as parallel imports, but with the difference that the trade is in drugs that have been authorised according to the centralised authorisation procedure. Unlike parallel distribution, parallel imports can only take place for medicinal products that have been authorised nationally or through mutual recognition.[227]

These different trading methods show how trade in medicinal products in the EU is highly influenced by the markets being divided between the Member States – companies, importers and distributors will find ways to get around differences in drug prices between EU Member States. Occasionally, parallel trade is restricted by national measures, such as requirements to state purchase costs, price regulation or burdensome authorisation procedures.[228]

Intellectual property etc.

In the pharmaceuticals sector, intellectual property primarily concerns patent protection and data protection (data exclusivity). In the EU, patent protection for pharmaceuticals is generally twenty years.[229] In addition to this, patent protection can be extended for another five years (Supplementary protection certificate).[230] Data protection – the protection that applies to data produced, for example, in the context of clinical trials – is valid for ten years in the EU (can be extended to a maximum of eleven years). Subsequently, generic drugs can be granted access to the market by referring to documentation from reference drugs, e.g. preclinical studies and clinical trials.[231]

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[224] See the FASS website: http://www.fass.se/LIF/publicdocuments?1&docId=79150.
[225] For medicinal products that have been authorised centrally, Regulation (EC) No 726/2004 applies. For nationally authorised medicinal products, Directive 2001/83/EC applies.
[226] Regulation (EU) No 1235/2010.
[227] See the FASS website: http://www.fass.se/LIF/publicdocuments?1&docId=79150.
[228] See for example the Commission's reasoned opinion to Greece http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2012-008805&language=EN.
[229] See the *European Patent Convention* (EPC) and Article 33 of the TRIPs Agreement.
[230] Regulation (EC) No 469/2009.
[231] See Article 10 of Directive 2001/83/EC. Note that medicinal products for veterinary use may be covered by data exclusivity for up to thirteen years. See Directive 2001/82/EC.

6.5.1.2 **The U.S.**

Agency structure

In the U.S., it is the federal agency, the *U.S. Food and Drug Administration* (FDA), which deals with the pharmaceuticals sector. The FDA works to ensure the safety and efficacy of drugs, the labelling of drugs as well as compliance with manufacturing standards in the production of drugs. The legal framework for pharmaceuticals in the U.S. is found in the *Federal Food, Drug, and Cosmetic Act* (FDCA). The FDCA is based on the Constitution's *Commerce Clause*, which means that the rules are applicable to the extent that the product or part of the product has been the subject to trade between at least two states. The FDA is, however, the only agency with the power to approve new drugs. In principle, no drug may be sold on the U.S. market without FDA approval – i.e. that the FDA has ensured that the drug is safe and efficacious.[232] By means of the *New Drug Application* (NDA) procedure, the FDA examines whether the drug can be approved for sale in the U.S. The starting point is an examination, through clinical trials, of whether the drug can be considered safe and efficacious, and whether the benefits of the drug outweigh the risks. The assessment also takes into account whether the manufacturing methods and area of use are adequate.[233]

Labelling

Once a product has been approved, the FDA's labelling regulations become relevant. The main principle is that drugs should be labelled on the basis of the areas of use for which the product has been tested. The label must also provide the physician with medically relevant information on how to use the product, for example with regard to dosage, warnings, and adverse reactions. The FDA imposes format requirements for labelling that must be observed by manufacturers. The final label shall accompany the product through a package insert that is primarily intended for the physician.[234] It is important to note that the FDA has no authority to regulate how a drug may be used. In other words, a physician can prescribe a drug for an area of use that is not listed on the FDA's approval labelling (known as “off-label”). However, the FDA may regulate the marketing of the product to the extent that the FDA may ban advertising that promotes a non-approved area of use for that product. This means that it is possible to sell a drug, on the order of a physician, which has not been approved for the area of use for which it is actually sold.[235]

Intellectual property and trade in generic drugs

The implementation of the *Hatch-Waxman Amendments*[236] in the FDCA constitutes the legal opportunity for generic drugs to gain approval without filing a complete application for approval (NDA, see above). This Abbreviated New Drug Application (ANDA) allows the FDA to rely on the assessment made for the reference drug with regard to safety and efficacy. The date when generics can enter the market is controlled by the reference drug's patent protection. In the approval of reference drugs, information is also submitted to the FDA on applicable patent protection. The FDA publishes patent terms (that is, durations) upon approval of the reference drug. The ANDA procedure also requires those applying for

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[232] Carter, Federal Regulation of Pharmaceuticals in the United States and Canada, Loyola of Los Angeles International and Comparative Law Review, 5-1-1999.

[233] See the FDA website: http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/newdrugapplicationnda/default.htm.

[234] Carter, Federal Regulation of Pharmaceuticals in the United States and Canada, Loyola of Los Angeles International and Comparative Law Review, 5-1-1999, p. 238.

[235] See guidelines on the FDA website: http://www.fda.gov/newsevents/testimony/ucm115098.htm. The equivalent in Sweden is called the “free prescription right” or “freedom to prescribe”.

[236] The original provisions are found in the Drug Price Competition and Patent Term Restoration Act.

generics trading approval to certify that the applicable patent for the reference drug has expired and to inform the patent holder of their intention to carry on trade in generics. If a dispute concerning patent infringement is initiated, the application is frozen for thirty months. The Hatch-Waxman Amendments also mean that certain early applications for generics trading can be granted market exclusivity for an initial period after the patent rights have expired.[237]

In the U.S., patents for pharmaceuticals are valid for twenty years from the date of filing.[238] Extension of the patent term by up to five years is possible through "patent term restoration". The U.S. uses the expression exclusivity, which means exclusive market rights granted by the FDA upon approval of a drug. Market exclusivity can run concurrently with the holding of a patent and aims to create a balance between the development of new drugs and competition from generic drugs. Market exclusivity may vary depending on the type of drug. For example, exclusivity for orphan drugs is seven years and for new chemicals, five years. The FDA uses the *Orange Book* to publish information on approved drugs and evaluations of therapeutic equivalence.[239]

6.5.1.3 **Global**

The *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use* (ICH) hosts an international cooperation between the EU, the U.S. and Japan to harmonise market authorisation requirements.[240] This cooperation began in 1990 and essentially aims to bring together agencies from the EU, the U.S. and Japan, as well as industry experts, in order to coordinate the technical requirements and develop manageable processes for developing new drugs. ICH consists of a steering committee and working groups with pharmaceuticals experts from the participating countries.[241]

So far, the working groups have produced about fifty guidance documents (ICH Guidelines) that are issued for adoption by the EMA in the EU, the FDA in the U.S. and the Japanese Ministry of Health, Labor and Welfare. ICH Guidelines prescribe common approaches in the areas of efficacy, quality and safety. ICH has, for example, produced guidelines relating to Good Clinical Practice (GCP) and preclinical testing. Perhaps the most important harmonisation measure is the *Common Technical Document* (CTD). The CTD enables applicant companies to only submit one dossier for approval that includes the necessary data for the EU, the U.S. and Japan.[242]

In the year 2000, 77 percent of the EU's pharmaceutical companies used ICH Guidelines. In the U.S. and Japan, the figure was over 80 percent. It is in many ways clear that the industry has benefited from common technical requirements through, for example, the avoidance of duplication, reduced time for developing new drugs and faster and more uniform approval procedures. Several other countries have also begun to apply ICH Guidelines, which means

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[237] See guidelines on the FDA website: http://www.fda.gov/newsevents/testimony/ucm115033.htm.
[238] See Article 33 of the TRIPs Agreement.
[239] See guidelines on the FDA website: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm.
[240] See the ICH website: http://www.ich.org/.
[241] Evenett and Stern, *Systemic Implications of Transatlantic Regulatory Cooperation and Competition*, p. 328.
[242] Evenett and Stern, *Systemic Implications of Transatlantic Regulatory Cooperation and Competition*, p. 328.

ICH Guidelines also have a harmonising effect globally.[243] There is also global cooperation on pharmaceuticals through the standardisation bodies' technical committees.

Cooperation also exists through the *Pharmaceutical Inspection Convention* (PIC) and the *Pharmaceutical Inspection Co-operation Scheme* (PIC/S). This organisation consists of 44 pharmaceuticals authorities worldwide that, among other things, regulate the interpretation of GMP regulations, conduct training programmes for drug inspectors and develop various cooperative forms.[244]

6.5.1.4 **Comparison**

There is a very great quantity of rules and standards that have a bearing on the pharmaceuticals sector in the EU and the U.S. These may relate to everything from managing clinical data, certification of safety and efficacy, procedures for marketing authorisation/approval and certification of Good Manufacturing Practice (GMP). It is accordingly difficult to give a complete picture of how the two regulatory systems relate to one another. Therefore, this comparison only identifies some general areas in the pharmaceuticals sector in which the EU and the U.S. differ.[245]

One of the most striking differences between the EU and the U.S. is that the EU market consists of national pharmaceuticals markets where Member States largely have the regulatory responsibility for ensuring that drugs are safe and efficacious. Each national drug authority has its own protocols and files that are not readily available to other drug authorities. Furthermore, there are linguistic differences between the Member States, the drug authorities might differ in the efficiency of their work processes, such as processing times, and might request their own national application forms and data in authorisation procedures. The U.S. does not have this kind of agency fragmentation and division between different national markets.[246]

One difference between the EU and the U.S. is that the U.S. has a more uniform way of approving generic drugs. The U.S. requires generic drugs to be able to demonstrate therapeutic and efficacy equivalence to the reference drug. In principle, the same requirements apply in the EU, but with the difference that the authorisation of generics in practice usually takes place nationally rather than being centralised as in the U.S. As part of efforts to avoid a fragmented internal market, the EMA and the Commission have taken a number of measures designed to facilitate the authorisation process for generics.[247]

Another significant difference is that it is common in the EU to have national rules on the pricing of drugs. In addition, different Member States apply different methods to regulate the prices of drugs nationally. The U.S. has, in principle, no corresponding rules. It is true that

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[243] Evenett and Stern, *Systemic Implications of Transatlantic Regulatory Cooperation and Competition*, p. 330.
[244] See the PIC/S website: http://www.picscheme.org/.
[245] Note that some of the most significant material differences are treated in the section on cooperative forms.
[246] Evenett and Stern, *Systemic Implications of Transatlantic Regulatory Cooperation and Competition*, pp. 319-320.
[247] See e.g. the EMA's measures to improve the transparency of data in clinical trials, http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/12/news_detail_001991.jsp&mid=WC0b01ac058004d5c1. See also the revision of the Transparency Directive, Council Directive 89/105/EC, http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/pricing-reimbursement/transparency/index_en.htm.

some U.S. states have instituted rules, e.g. to subsidise drugs for buyers who are unable to buy prescription drugs, but from an overall perspective, the EU Member States regulate pricing in a much more vigorous way than U.S. states do.[248]

6.5.2 Uncertainties/Barriers to trade

There are many factors that affect the pharmaceuticals trade between the EU and the U.S. Some uncertainties can be traced to insufficient regulatory coherence between the EU and the U.S., e.g. regarding the conditions for the authorisation/approval of generics, scientific regulations that have a bearing on research and preclinical testing and the reporting of adverse reactions in individual situations. Other uncertainties can be linked to the structural and market differences that exist between the EU and the U.S. The EU consists of several Member States with a relatively significant national competence, which means that the regulatory framework has elements both of centralised and decentralised procedures, while the U.S. is more clearly characterised by uniformity resulting from its federal context.

One problem identified in the literature is that pricing and purchasing of drugs by the Member States, together with the national pharmaceuticals authorities' competence to grant and reject applications for market authorisation, create fragmented EU procedures and fragmented markets.[249] However, it is clear that the Commission and the EMA have taken progressive measures to hold together the European pharmaceuticals market and the implementation of the regulations. This has taken place both through a significant European harmonisation and through investigations and guidelines with regard to how the national management can be coordinated and streamlined.[250] One uncertainty that in this regard may apply to the U.S. is that the FDA, in comparison with national agencies in the EU, has less experience of working out the consensus solutions that are often necessary to achieve effective bilateral agreements. This might cause the cultural differences that exist to become more difficult to bridge.[251]

Based on ICH cooperation, which may generally be described as a success, it is possible to see signs to suggest that ICH Guidelines are interpreted differently between different regulatory agencies. It is likely that similar problems of interpretation should also be raised in the event of deeper cooperation between the EU and the U.S. Although the conditions for reaching agreement on common methods and approaches are good, this need not mean that these guidelines are interpreted and applied in a similar manner.[252] It is in other words important that there are explicit means to achieve a uniform interpretation and application between the various agencies.

In this connection, mention may also be made of the existing mutual recognition agreement between the EU and the U.S. The agreement may generally be described as unsuccessful as it

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[248] Evenett and Stern, *Systemic Implications of Transatlantic Regulatory Cooperation and Competition*, pp. 322-323.
[249] Evenett and Stern, *Systemic Implications of Transatlantic Regulatory Cooperation and Competition*.
[250] In addition to the substantive harmonisation measures mentioned above, the Commission is working to improve transparency http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/pricing-reimbursement/transparency/index_en.htm.
[251] Comment from the Swedish Medical Products Agency.
[252] Evenett and Stern, *Systemic Implications of Transatlantic Regulatory Cooperation and Competition*, p. 326.

did not function as intended.[253] The agreement was based on six sectoral annexes containing provisions on, e.g. mutual recognition of facility inspections (GMP). In practice, it was difficult to apply the agreement as it was, among other things, impracticable for the FDA to examine the various Member States' regulations that were to be the subject of recognition.[254] Thus, a prerequisite for effective cooperation is that the different technical requirements are coordinated as far as possible within the Union. This is something that has now taken place as there has been a significant harmonisation since the MRA was signed in 1997.

Another factor that should be mentioned is the differences that exist for intellectual property. Patent law differs substantially between the EU and the U.S., which has an impact on the conditions for companies to trade across the Atlantic. Harmonised patent legislation is a complex issue that will be difficult to resolve in the context of TTIP. However, it is to be noted that the U.S. has amended its *first to invent* doctrine into something that is broadly similar to that used in the EU, *first to file*.[255] The issue of data protection is also relevant if the EMA and the FDA are to cooperate in their assessments and share information with each other, e.g. in authorisation/approval procedures and references to existing data from previously approved reference drugs. Increased cooperation between the EU and the U.S. will probably demand common rules for data protection.

Finally, mention may also be made of the uncertainty of deeper agreements between the EU and the U.S. that are reached outside existing global structures, such as ICH. It is important that TTIP does not have the effect of undermining these procedures. If this were to be the case, the agreement would harm existing harmonisation processes that apply globally.

6.5.3 Cooperative forms

This part mainly describes the views received by the National Board of Trade from the industry association, LIF - the research-based pharmaceutical industry in Sweden, and from the Medical Products Agency (MPA). The views received are based on the development areas identified by the Commission as well as the positions on these issues put forward by the European industry. An important issue in this context is the mutual recognition of GMP inspection and biosimilars.

In contrast to the inadequate MRA, there is ongoing cooperation between the EMA and the FDA in the area of *manufacture, import and distribution of active pharmaceutical ingredients (API).* The cooperation aims to harmonise inspection and information exchange on API manufacturing. According to the MPA, this is an example of an alternative to the mutual recognition agreement.

As regards the proposal of *parallel scientific advice*, the MPA emphasises that in practice there already exists a consensus in mature therapeutic areas and that the EMA in principle always takes previous FDA advice into account. For advice on therapeutic areas in which there is limited experience, the advice should be based on harmonised development programmes. According to the MPA, in the context of scientific advice, the FDA tends to approve certain drugs at different times to the EU. It might also be the case that the FDA and

[253] The agreement may today be described as “not in operation”, see http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/mutual_recognition_agreements.jsp&mid=WC0b01ac058006e013.
[254] Evenett and Stern, *Systemic Implications of Transatlantic Regulatory Cooperation and Competition*, p. 326.
[255] See the United States Patent and Trademark Office website, http://www.uspto.gov/aia_implementation/faqs_first_inventor.jsp.

the EMA make different assessments in borderline issues. This stems from questions of valuation and not from a disparate approach to drug development. One proposal is to have good transparency and the possibility to respond to advice before it is fully drafted. A reasonable goal might be to produce advice that is not contradictory, but that may vary in scope.

In the area of *paediatric medicines*, there are sometimes different views between the EMA and the FDA regarding paedriatic investigation plans (PIP). According to the MPA, there are companies that indicate that they are planning to conduct studies based on scientific advice from the FDA and with which the EMA does not always agree. This can lead to the development of medicines for children being delayed or impeded. In order to prevent this, there has been cooperation between the EMA and the FDA through regular teleconferences that raise specific matters. The MPA supports this cooperation and encourages measures to simplify procedures and the development of medicines for children.

In the current situation, the EU and the U.S. have different views on how safety reporting, *pharmacovigilance*, is to be designed. The MPA stresses that it can be difficult to mutually recognise each other's systems, procedures, advice and guidelines if this lacks support in EU and U.S. legislation. The cooperation should be focused on creating harmonised, common and coordinated pharmacovigilance. A development of this kind could be achieved through an ongoing, fast and complete exchange of information between the EU and the U.S. This would probably require confidentiality agreements and the ability of the Member States and the FDA to jointly utilise the expertise available. The MPA notes that pharmacovigilance-related advice can be rendered more difficult if the drugs have undergone different types of authorisation processes (see above) within the EU, because legislation can differ in the EU for national market authorisation procedures. For this reason, the advice requires more explicit coordination, either through more uniform legislation or through the focusing of the advice on identifying common denominators. Regarding the format of current periodic reports, the MPA notes that the FDA officially accepts the PSUR format, the format used in the EU. In addition, the FDA has its own reports as a complement. The MPA stresses the importance of both parties following a common format in practice. Another aspect is that the EU today has departed from PSUR requirements for certain drugs, such as generics. In the U.S., safety reports are to be submitted for all approved drugs.

The MPA notes that the EU and the U.S. largely have a harmonised regulatory framework for *change requests.* The U.S. does not have as detailed guidelines as the EU. In the EU, the guidelines have to be interpreted by several Member States, which means that the regulations are not as flexible as in the U.S. For this reason, the FDA must introduce a more strict regulation in order to deepen the cooperation.

As regards *results of clinical trials*, LIF emphasises that TTIP should ensure that both the EU and the U.S. retain a uniform protection of patient integrity, integrity of the regulatory process and of the commercial interests of applications both for clinical trials and marketing authorisation.[256] LIF states that it is somewhat unsure of how developments are progressing in the area of *falsified medicines.* In the EU, there is a Directive in the area.[257] The Directive is awaiting specifications, among other things, on how delegated acts will set out the characteristics and technical specifications of “unique identifiers”. According to the EC, these will probably be given in late December 2014 or early January 2015. The EU has also announced that “track and trace” will not come into question. There are indications to

[256] LIF refers to EFPIA and PhRMA's joint policy: http://phrma.org/sites/default/files/pdf/PhRMAPrinciplesForResponsibleClinicalTrialDataSharing.pdf.
[257] Directive 2011/62/EU.

suggest that the U.S. has decided to use “track and trace”. Developments thus appear to be going in two different directions.

In the area of *pharmacopoeia*, the MPA emphasises the cooperation in Europe through the Council of Europe's Convention on the Elaboration of a European Pharmacopoeia (European Treaty Series (ETS), No. 50, 1964).[258] The United States Pharmacopeia (USP) is a private organisation that is non-profit. Harmonisation work is in progress between the Ph. Eur., USP and the Japanese Pharmacopoeia. A global pharmacopoeia cooperation has also recently been launched. This is therefore not a matter that can be resolved by the EMA and the FDA alone.

In conclusion, LIF emphasises that, in its capacity of research-based pharmaceutical companies, it is highly dependent on incentives to develop new and innovative medicines. This includes a strong *intellectual property system*, especially in the area of patents, and a strong system for *enforcement.* According to LIF, TTIP provides the opportunity to affirm and strengthen these systems, to seek greater convergence between the respective systems, and to support the underlying principles and standards for protection in the parties' respective trade agendas and trade negotiations with third countries. LIF states the following areas for greater convergence:

1. (a) protection of regulatory data, (b) transparency of regulatory data, (c) regulatory approval of trademarks, (d) substantive patent law harmonisation, (e) enforcement of patent rights, (f) IP chapter in trade negotiations with third countries.

Furthermore, LIF states that support of the parties' underlying principles and standards in the IP area embraces:

2. (a) criteria and standards for patentability, (b) ensuring that only patent offices and courts shall have the right to decide in patentability issues, (c) ensuring effective patent term, (d) ensuring that restrictions on trademarks intended for medicines are imposed solely on the basis of patient safety issues.

6.5.3.1 **Conclusions**

Based on the contacts that the National Board of Trade has had with the parties concerned, it appears, subject to the distinctions made above, that they will comply with the proposals submitted by the Commission. From a regulatory perspective, several proposals receive support. At the same time, there are questions about how the cooperation will be designed in practice – partly because there are existing and functioning international cooperations (e.g. ICH), and partly because the previous agreement was fruitless. Some questions have also been raised regarding the FDA's ability to relate constructively to the EMA and common guidelines, especially in borderline situations. The industry, on its part, has been careful to emphasise that any increased cooperation must take intellectual property protection into consideration. Almost all the cooperation areas highlighted are based on proposals to improve transparency between the EU and the U.S. and to facilitate procedures to bring both parties' agencies, the EMA and the FDA, closer to each other. Also mentioned are common procedures for rule simplification and facilitation measures for the development of new drugs.

[258] This cooperation involves 37 Member States and the EU, which have signed the Convention. The European Pharmacopoeia cooperation also has the involvement of 24 observer states, including 17 outside Europe, as well as WHO.

In view of the earlier and unsuccessful MRA, the National Board of Trade notes that mutual recognition should start out in areas where there is a relatively strong similarity in the requirement level between the EU and the U.S., i.e. that a process of harmonisation has taken place, perhaps on another, bilateral or international, plane. In areas where the EU and the U.S. are further apart, new and progressive harmonisation measures should be introduced. This would have the aim of approximating the regulatory frameworks and ultimately simplifying mutual recognition. Furthermore, it is important that the rules that are harmonised, or that are about to be harmonised, are actually entered into the national legislations. This also applies to the procedures for mutual recognition. This will lend weight to the proposals, while avoiding situations where agencies cannot apply mutual recognition.

6.6 Medical devices sector

Medical devices encompass a great number of different products that are used for healthcare purposes. The product area ranges from simple bandages, surgical blades, operating tables, hospital beds and wheelchairs, to more sophisticated instruments, such as pacemakers, hip implants, infusion sets and pumps for drug delivery. Information systems used for healthcare may also constitute medical devices. A recurring characteristic of medical devices is that they are intended in some way to detect, prevent, monitor, treat or alleviate diseases, injuries or disabilities. Certain products used for birth control purposes can qualify as medical devices.

Increased trade and coordination of medical device regulation can generate many benefits to society, such as reduced costs for medical devices through increased supply and better access to diverse and innovative products for patients. The foremost barriers to transatlantic trade are primarily different types of dual burdens, which mean that manufacturers have to undergo registration, testing, etc. both in the EU and the U.S. in order to market their products.

The following section describes the overarching characteristics of European and American regulation of medical devices, as well as potential uncertainties and forms for transatlantic regulatory cooperation. The section follows a structure which entails that the respective sections (regulation in the EU and the U.S. respectively, uncertainties/barriers to trade and cooperative forms) deal with the same aspects. These aspects have been identified partly by the overall regulatory structure, but also by specific issues that have been raised in the negotiations and that have come to the attention of the National Board of Trade following investigation and contacts with various stakeholders. The following aspects have been identified: pre-market control and classification, standardisation, market surveillance and, traceability. Some parts also raise other aspects.

6.6.1 Regulatory model

6.6.1.1 **The EU**

The European regulatory framework for medical devices has been gradually harmonised since the early 1990s through the Medical Devices Directive[259], which is complemented by the AIMD Directive[260] for implantation devices and the IVD Directive[261]. The directives are 'New Approach' directives, which mean that they lay down essential requirements for the construction and manufacturing of medical devices that can be fulfilled through substantive requirements in harmonised standards. The area of application is very broad and comprises the majority of products used for healthcare purposes. Some notable exceptions are implants for purely aesthetic purposes[262] and certain information systems that do not fall within the definition.[263] The directives entail far-reaching harmonisation, but are not exhaustive. This means that there are some opportunities for national agencies to stop certain products and apply additional requirements.[264]

Some studies describe the European regulation of medical devices as successful, and the simplified authorisation procedures (compared with e.g. the U.S.) have been attributed to be a factor that has generated growth in innovation and testing in the EU.[265] However, some argue that simplified market access has come at the expense of patient safety.[266]

The legal basis for the medical devices directives is Article 114 TFEU, which means that the regulations have the overall objective of creating a common market for medical devices in the EU. However, the Directives also aim for "the maintenance [and] improvement of the level of protection attained in the Member States" for medical devices.[267] The patient safety aspect is a central part of the European regulation of medical devices[268] and is an interest that must be weighed against the need to rapidly market new medical devices.

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[259] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

[260] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.

[261] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

[262] Such products are described in the Commission's proposal for new Regulations as "invasive products without a medical purpose that are similar to medical devices in terms of characteristics and risk profile", see: COM(2012) 542 final, p. 4.

[263] Medical Products Agency, *Medicinska informationssystem – vägledning för kvalificering och klassificering av programvaror med medicinskt syfte*, 2012. Available at: http://www.lakemedelsverket.se/upload/lvfs/vagledningar/vagledning_medicinska_informationssystem_2012-11-061.pdf.

[264] Sweden has, among other things, requirements for labelling and use instructions to be in Swedish, which is permitted under the Directives: the AIMD Directive, Article 4L; the Medical Devices Directive, Article 4; the IVD Directive, Article 4.

[265] See among others: K. H. Kruger and M. A. Kruger in "The Business of Healthcare innovation", ed. L R Burns (Cambridge, Cambridge University Press) 2012, p. 444; California Healthcare Institute and Boston Consulting Group, "Competitiveness and regulation: The FDA and the future of America's biomedical industry" (2011). Available at: https://www.bcgperspectives.com/Images/BCG_CHI_Competitiveness_and_Regulation_Feb_2011.pdf.

[266] D. Cohen and M. Bilingsley, "Europeans are left to their own devices" (BMJ 2011;342:d2748). Available at: http://www.bmj.com/content/342/bmj.d2748.pdf%2Bhtml.

[267] Medical Devices Directive, Preamble, Recital 5.

[268] Since the Lisbon Treaty entered into force, there is a new legal basis for the regulation of medical devices: Article 168(4)(c) TFEU. The article prescribes that the Union shall adopt "*measures setting high standards of quality and safety for medicinal products and devices for medical use*".

Pre-market control and classification

In order to place a medical device on the market, the manufacturer (or the distributor) must ensure that:

- the product, depending on classification, conforms with the essential requirements set out in the annexes of the directives and that this can be demonstrated by adhering to the applicable procedures, where different degrees of involvement by notified bodies is required dependant on classification,
- there is a technical file for the product,
- the product is evaluated on the basis of clinical efficacy and possible adverse reactions, founded on clinical studies,
- where applicable:[269] the product is registered with the national competent authority where the manufacturer or designated representative is established,
- the product is subject to reporting requirements in the event of accidents and incidents (medical device vigilance system), and,
- the product is CE marked.

Conformity with the essential requirements means, among other things, that the products must undergo clinical evaluation.[270] It also means that manufacturers must have adequate quality management systems. In brief, quality management systems mean that manufacturers ensure that there is sufficient documentation on matters including technical information, reporting procedures in the event of accidents and incidents, the existence of quality programmes, etc. The quality management systems should be continuously evaluated by the *notified bodies* to ensure that the manufacturer fulfils the requirements of the directives. The notified bodies, designated by the Member States, bear the primary responsibility for the assessment of the medical devices' conformity with the requirements of the directives, and of the adequacy of manufacturers' quality management systems.[271] The directives do not prescribe how the Member States designate notified bodies, but establish requirements that the bodies must meet to become designated.[272] In Sweden, the notified bodies are designated, following application and accreditation, by *Swedac* in consultation with the *Medical Products Agency*. It is also Swedac who bears the primary responsibility for exercising supervision over the notified bodies,[273] although this is to be done in consultation with the Medical Products Agency.[274] In Sweden, there are two notified bodies for medical devices: *SP Technical Research Institute of Sweden* and *Intertek Semko AB.*

Medical devices are classified depending partly on the product category to which they belong (medical devices, IVD devices, and active implantable medical devices) and partly on

[269] Medical Devices Diretive, Artice 14.1
[270] AIMD Directive, Annex 7; Medical Devices Directive, Annex X.
[271] AIMD Directive, Article 11; Medical Devices Directive, Article 16; IVD Directive, Article 15.
[272] AIMD Directive, Annex 8; Medical Devices Directive, Annex XI; IVD Directive, Annex IX.
[273] Section 7 of the Act (2011:791) concerning Accreditation and Conformity Assessment; the Swedish Board for Accreditation and Conformity Assessment's (Swedac) Regulations and General Guidelines for notified bodies (STAFS 2011:5, consolidated version).
[274] Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (OJ L 253, 25.9.2013, p. 8), Article 9.

the risk category to which they belong.[275] Classification is important because it determines how extensive the conformity assessment procedure will be before the device can be placed on the market.[276] However, AIMD devices must always undergo an extensive conformity assessment procedure. For certain products that border between categorisation as medical devices or pharmaceutical products for human use[277], the Member States have the possibility of classifying the product in question differently on the basis of scientific evidence.[278]

With respect to classification and category, the manufacturer has certain opportunities to choose the procedure that will be applied to the medical device to be marketed.[279] In brief, this means that the higher the risk category a product is in, the higher the demands that will be placed on testing and clinical data in the various stages of manufacturing. The system of risk classification and the ability of manufacturers to choose procedure are based on the New Approach, with modules that are described in the respective directive.

A product that conforms to the essential requirements can be marketed freely after being CE marked, subject to certain national requirements. It is only non-sterile Class I devices, or Class I devices withouth measuring functions, according to the Medical Devices Directive and certain IVD devices that can be CE marked and marketed wholly without the involvement of a notified body, but it is always the manufacturer's own responsibility to ensure that the devices conform to the Medical Devices Directive.

Standardisation

For existing technologies and quality management systems, it is possible to demonstrate conformity with the essential requirements by applying harmonised standards, such as those produced on behalf of the Commission and EFTA by the European standardising organisations CEN, CENELEC and ETSI.[280]

Market surveillance

Market surveillance in Europe is divided among national competent authorities and notified bodies. In brief, the division means that the national agencies have overall responsibility for the implementation of the directives at the national level. Competent authorities are primarily responsible for follow-up when manufacturers report accidents and incidents in conjunction with the use of medical devices (“medical device vigilance system”). On the basis of this information, the competent authorities can take action and, if necessary, take temporary or permanent measures to restrict the marketing of a medical device. Competent authorities also have opportunities in other cases to restrict the marketing of certain medical devices, regardless of whether the device meets the essential requirements of the directives, if it can be shown that patient safety is at risk during use.[281]

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[275] Medical Devices Directive, Article 9(1) The Directive has four classes: low risk (Class I), medium-low risk (Class IIa), medium-high risk (Class IIb) and Class III (high risk). AIMD devices are, de facto, high risk and are therefore included in Class III; IVD Directive, Article 9(1-2). The Directive distinguishes between IVD devices referred to in Lists A and B and devices for self-testing and other IVD devices.

[276] Medical Devices Directive, Article 11; IVD Directive, Article 9.

[277] According to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

[278] ECJ ruling in Case C-109/12, *Laboratoires Lyocentre*, (2013) p. 47.

[279] AIMD Directive, Article 9; Medical Devices Directive, Article 11; IVD Directive, Article 9.

[280] See further: http://www.lakemedelsverket.se/malgrupp/Foretag/Medicinteknik/Vagen-till-CE-market/Standarder-/ and http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/medical-devices/.

[281] AIMD Directive, Articles 7 and 10(c); Medical Devices Directive, Articles 8 and 14 (b); IVD Directive, Articles 8 and 13.

In Sweden it is the Medical Products Agency that is the competent authority and which therefore has the prerogative to ensure that the Medical Devices Directives are implemented in Sweden by adopting necessary regulation and market control measures.[282]

Re-regulation of the European regulatory framework
On November 26, the Commission presented two proposals for new regulations aimed at more uniform application of the regulatory framework.[283] The regulation proposals will entail consolidation of the AIMD and Medical Devices Directive into one statute, while IVD devices will be governed by a separate regulation. However, the significant horisontal aspects linked to market control and surveillance will be more or less identical in both statutes.

The proposal is founded on Articles 114 and 168(4)(c) TFEU, and has the stated aim of guaranteeing high patient safety and access to innovative medical devices. The most significant change relates to stricter competence requirements for notified bodies, who, according to the Commission, have been criticised for differences in output with regard to the monitoring of quality management systems and conformity assessment.[284]

The regulatory changes are also intended to reflect the ongoing global harmonisation work of the *International Medical Device Regulators Forum* (IMDRF) (see more below) and therefore propose traceability requirements through product identification, *Unique Device Identification* (UDI).

The proposals are currently being examined by the Council of the European Union. According to officials at the Medical Products Agency, the process will probably continue until at least 2015 before the new regulations are adopted.

6.6.1.2 **The U.S.**

In contrast to current European regulation,[285] the U.S. regulation of medical devices is based, on the one hand, on the explicit goal of quick access to new medical devices and, on the other hand, patient safety.[286] It is U.S. Code Title 21 that regulates food, narcotic drugs, medicines and medical instruments.[287] Detailed technical regulations are established by the federal market surveillance agency, the *U.S. Food and Drug Administration* (FDA), in the *Code of Federal Regulations* (CFR).

[282] See in particular Section 11 of the Medical Devices Ordinance (1993:876); Consolidated version of the Swedish Medical Products Agency's regulations (LVFS 2003:11) on medical devices.
[283] COM (2012) 542 final, "Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009", COM(2012) 541 final, "Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices".
[284] COM(2012) 541 final, p. 6, COM(2012) 542 final, p. 7.
[285] Current European regulation does not have the explicit aim of providing rapid access to new medical devices. However, in the proposed regulations, it is submitted that the regulatory framework should promote innovation. See: COM(2012) 542 final, preamble 1.
[286] Congressional Research Service, *FDA Regulation of Medical Device*s, (2012) p. 2.
[287] See in particular: United States Code (U.S. Code) Title 21 (USC 21) Chapter 9, *Federal Food, Drug, and Cosmetic Act* (FDCA).

Pre-market control and classification

In the U.S., all manufacturers of medical devices must register with the FDA, provide product lists and follow certain common control provisions.[288] The common control provisions entail that all medical devices, before marketing, must:

- be linked to establishment registration (applicable to manufacturers, distributors, companies that repackage or relabel devices as well as foreign companies)[289],
- be listed with the FDA,
- be manufactured in accordance with good manufacturing practice (GMP), which includes provisions on quality management systems[290],
- be labelled[291], and
- be reported to the FDA through registration, clearance or premarket approval (see below).[292]

As in Europe, the U.S. has a classification system, but IVD devices and active implantable medical devices are not subject to separate regulation. Classification determines the pre-market controls that are necessary for placing a product on the market as well as the post-market controls. In brief, classification means that devices with a higher risk classification are covered by more stringent pre-market and post-market controls, including requirements for quality management in manufacturing. The majority of medical devices that fall within Class II, and certain products within Class III, can be placed on the market without being tested for clinical safety and efficacy through the *510(k) procedure.* The 510(k) procedure means that a manufacturer demonstrates that the device has a function that corresponds to an existing device (predicate device). The FDA may then, on the basis of technical data submitted by a manufacturer, choose to clear the product in question. The 510(k) procedure is also available if a manufacturer places a device on the market which is a modified version of a predicate device. Although the 510(k) procedure means that the FDA must clear the devices, self-certification and third-party certification play a role in the procedure.

High-risk devices and certain new devices require the FDA's *premarket approval* (PMA). This is the most rigorous testing procedure and requires the manufacturer to demonstrate that a medical device is safe and efficacious for its intended area of use. Premarket approval typically requires clinical data for the application.[293] Unlike in the EU, the FDA does not test the devices in question, but only examines the information that the manufacturer sends to the FDA. The FDA does, however, conduct inspections of manufacturing facilities to ensure that the manufacturer has adequate quality management systems.[294] Another important difference, in contrast with the European system. is that the FDA may convene an advisory committee that submits a scientific and policy-related statement on the device in pre-market controls. The Commission has proposed a similar system, which could mean that notified bodies in the future must notify an expert committee when examining high-risk devices.[295]

[288] 21 Code of Federal Regulations (CFR) 862-892.
[289] 21 CFR, 807.20.
[290] 21 CFR 820.
[291] 21 CFR 801 or 809.10.
[292] Low-risk devices, such as bandages and ice bags, must only be registered and not undergo premarket approval. However, other products require premarket approval (PMA) or a 510(k) review.
[293] 21 CFR 814.
[294] 21 CFR 820; inspections can also be carried out by accredited bodies.
[295] COM(2012) 542 final, p. 6, COM(2012) 541 final, p. 7.

Standardisation
A manufacturer applying a standard that has been accepted by the FDA (consensus standard) can be awarded with reduced demands on technical data and documentation for a 510(k) application, which facilitates processing by the FDA.

Market surveillance
As the market surveillance agency, the FDA is responsible for classification and for pre-market and post-market controls of devices and quality management systems. In similarity with EU regulation, there is a system for reporting serious incidents associated with the use or misuse of medical devices (adverse event reporting).[296] Manufacturers are therefore required, within certain time frames, to report adverse events to the FDA. In addition, the FDA has far-reaching powers to ensure regulatory compliance and can decide on device recall. If a manufacturer does not voluntarily recall a device, the FDA may use several different legal remedies, including criminal sanctions.[297]

Re-regulation
The FDA has initiated a project that aims to analyse risks arising from the use of medical devices, as a complement to the reporting responsibilities of manufacturers. The system (Sentinel System) is proactive and is based on patient databases. It will be used to identify risks that are not revealed through existing reporting mechanisms.[298]

The FDA is also currently implementing *Unique Device Identification* (UDI). This system will be phased in over a five-year period and it is primarily Class II and III devices that will be covered by the requirement for unique device identification. The administration and allocation of UDI codes will be done by private bodies accredited by the FDA.[299]

Multilateral and bilateral regulatory cooperation
The *International Medical Device Regulators Forum* (IMDRF) is a global forum for regulatory cooperation. Its members are Australia, Brazil, Canada, the EU, Japan and the U.S. China and Russia intend to become members, and the World Health Organisation has observer status.[300] IMDRF was established in 2011 and has assumed the work previously conducted within the framework of the *Global Harmonisation Task Force* (GHTF).[301] IMDRF does not yet adopt binding international agreements, but the organisation has produced guidelines and studies on pre- and post-market controls, quality management systems, the auditing of such systems and clinical performance and safety.[302] Work is currently underway to develop a global incident reporting system, the *National Competent Authority Report Exchange* (NCAR), UDI systems, common requirements for assessing the competence of bodies that examine manufacturers' quality assurance systems, recognised international standards as well as a platform for joint device applications.[303]

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[296] Medical Device Reporting (MDR), see: FDCA § 519(a).
[297] FDCA §§ 516-520.
[298] See: http://www.fda.gov/Safety/FDAsSentinelInitiative/Default.htm.
[299] GS1 US and the Health Industry Business Communications Council (HIBCC) are currently the accredited bodies for the allocation of UDI codes, see: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm?utm_source=MembersOnly+Updates&utm_campaign=c7c1e8c870-Proposed_Rules_7_5_2012&utm_medium=email.
[300] See further: http://www.imdrf.org/about/about.asp.
[301] See further: http://www.ghtf.org/.
[302] http://www.imdrf.org/documents/documents.asp.
[303] http://www.imdrf.org/workitems/work.asp.

Both the EU-South Korea and the EU-Singapore free trade agreements contain annexes on cooperation on drugs and medical devices,[304] which in many ways are similar. Both FTAs state that the parties are to use global standards and guidelines developed by international cooperation bodies such as IMDRF.[305] In this respect, the EU-South Korea FTA clearly states that the purpose of international cooperation is to facilitate regulatory cooperation between the EU and South Korea.[306]

However, neither of the agreements establishes common technical regulations. The EU-South Korea FTA contains a provision to the effect that the parties are to consider every request to accept conformity assessment. However, the provision includes a reservation to the effect that this should only be done as long as "both Parties' corresponding practices are in accordance with international practices".[307] However, the EU-Singapore FTA lays down that both parties are to discuss opportunities for a mutual approximation of authorisation procedures where possible. Although the FTAs lack common technical regulations, they do lay a foundation for consultation on such provisions, among other things through transparency mechanism for all regulation of medical devices, not only technical regulations.[308]

Both FTAs establish common provisions for the elimination of non-tariff barriers linked to public intervention. For this reason, there are provisions on non-discrimination in conjunction with the listing, pricing or public reimbursement of medical devices.[309]

6.6.1.3 **Comparison**

The regulatory frameworks for medical devices in the U.S. and the EU are similar as both systems strive for a high level of patient safety and entail requirements on pre-market controls for all devices that are associated with certain risks. One important difference on a structural plane is that rule changes in the CFR can be implemented more rapidly than changes to the European regulatory framework. This is because it is the FDA that can initiate changes following a public consultation round. The European legislative process is much more complex and involves many different interests, which means that regulatory changes may be more cumbersome.

Classification

Both the EU and the U.S. have classification systems for medical devices. The classification systems correspond to each other to some extent, but not fully. In addition, the EU has three categories of medical devices (medical devices, active implantable medical devices and IVD devices).

Pre-market control

The most significant difference in pre-market controls lies in the requirements on technical documentation for placing devices in the respective markets. In the EU, all manufacturers, except for those releasing low-risk devices, must undergo third-party certification and demonstrate that their devices meet the essential requirements of the directives. In the U.S., it is possible for most devices evaluated through the 510(k) procedure to demonstrate that the device, in all material respects, is equivalent to an existing device on the market without

[304] Council Decision 2011/265/EU of 16 September 2010.
[305] EU-South Korea FTA, Annex 2-D, Article 1(f); EU-Singapore FTA, Annex 2-C, Article 2.
[306] EU-South Korea FTA, Annex 2-D, Article 5.1.
[307] EU-South Korea FTA, Annex 2-D, Article 5.2.
[308] EU-South Korea FTA, Annex 2-D, Article 3.1; EU-Singapore FTA, Annex 2-C, Article 3.
[309] EU-South Korea FTA, Annex 2-D, Article 2; EU-Singapore FTA, Annex 2-C, Article 3.3.

further testing. This is an important difference as the FDA accepts that manufacturers conduct conformity assessments themselves,[310] which is only possible for low-risk devices in the EU.

In practice, this has little impact on the substantive assessment, and several commentators point out that certification in the EU is generally faster than clearance in the U.S., regardless of whether it relates to existing or new technologies.[311] High-risk devices have relatively extensive requirements on testing and technical documentation both in the EU and in the U.S.

Regardless of category or risk classification, both the EU and the U.S. require manufacturers to have quality management systems. The EU applies ISO standard 13485, and the U.S. applies GMP as evaluated by the FDA or an accredited body. The quality management systems are in some cases evaluated in connection with the marketing of high-risk or innovative devices, but for all manufacturers, there are requirements for quality management systems to be continuously audited.

Standardisation

Although standardisation policy differs between the EU and the U.S., there are certain similarities in the medical devices sector:

In the EU, manufacturers can demonstrate conformity with the essential requirements of the Directives by applying harmonised standards. Similarly, in the U.S., the FDA drafts lists of consensus standards, which manufacturers can implement to facilitate the release of devices going through the 510(k) procedure. The major difference lies in the fact that European harmonised standards largely consist of ISO/IEC standards, whereas the U.S. system also accepts national U.S. standards. According to one notified body that the National Board of Trade has been in contact with, common international standards in terms of the devices' core functionality are used to a great extent, while there may be differences in ancillary functions, such as electricity supply.

Product supervision

Manufacturers are required to report incidents in the use of medical devices, both in the EU and the U.S. Both parties also participate in the global exchange of incident reports.

Traceability

Within the EU, the Commission has proposed that all medical devices, with some variation depending on the device's risk classification, be assigned a UDI.[312] In the U.S., the FDA has already adopted UDI provisions, which will enter into force from 23 December 2013.[313]

[310] FDA, *Guidance for Industry and FDA Staff – Recognition and Use of Consensus Standards*, 2007.
[311] The Business of Healthcare innovation, p. 444.
[312] COM(2012) 542 final, p. 7, COM(2012) 541 final, p. 5.
[313] 21 USC § 360i(f); Unique Device Identification System, final rule (78 FR 58785). Available at: https://www.federalregister.gov/articles/2013/09/24/2013-23059/unique-device-identification-system#h-56.

6.6.2 Uncertainties/Barriers to trade

In its study, the Commission has indicated that the transatlantic trade in medical devices generally functions well. Most of the devices certified in the EU, or cleared/approved in the U.S., may also be sold on the other market because they meet safety levels that are essentially similar.[314] After contact with the Medical Products Agency, industry associations and individual companies, the impression of the National Board of Trade is that this is a fair view. However, there are a number of uncertainties that could be addressed to improve conditions for individual companies placing medical devices on both sides of the Atlantic.

Classification

A recurring comment from various actors in the medical devises sector is that the divergent classification systems generate additional costs and uncertainty regarding regulatory compliance.

Pre-market controls

The substantive requirements of the EU and the U.S. are similar in terms of safety and performance levels for the majority of medical devices. With the exception of individual devices and materials that are prohibited in the respective markets, there are no obvious barriers to the placing of medical devices in both markets.

However, what does generate additional costs and inefficiency, which may especially discourage small manufacturers, is dual burdens arising in the release of medium-risk and, in particular, high-risk devices, as well as innovative devices, in both markets. A mutual recognition agreement currently exists between the EU and the U.S. that includes medical devices, but this agreement has not been implemented. This means that manufacturers wishing to release medical devices of medium and high risk both in the EU and the U.S. have to undergo dual procedures for the assessment of conformity. Manufacturers are also affected by dual burdens through registration requirements, both in the EU and the U.S.

In addition, one problem that has been highlighted is slow administrative procedures at the FDA, especially for high-risk and innovative devices. The U.S. system of 510(k) clearance may give the impression that it provides easier access to the market because it is sufficient for the manufacturer to demonstrate that a device is equivalent to an existing device on the market. In practice, however, the processing times for medium-risk devices are similar in the EU and the U.S., even though the EU requires product testing.[315]

The literature emphasises that U.S. requirements are more far-reaching for high-risk and innovative devices. According to A.G. Fraser et al., this is among other things due to the fact that the FDA not only has a mandate to exercise supervision over the placing of devices on the market, but also has a supervisory responsibility with respect to device usage.[316] This may be compared with the notified bodies that have no supervisory responsibility for the use of the devices. The stricter requirements in the U.S. have led to a situation where many manufacturers first release a high-risk device in the EU, accumulate clinical documentation

[314] The Commission, *Non-Tariff Measures in EU-US Trade and Investment – An economic analysis*, p. 165.

[315] Kramer, *Regulation of Medical Devices in the United States and the European Union*, The New England Journal of Medicine (2012). Available at: http://www.nejm.org/doi/full/10.1056/NEJMhle1113918; DL Gollahel and S. Goodall, *Competitiveness and regulation: The FDA and the future of America's biomedical industry*, (2011). Available at: http://www.bcg.com/documents/file72060.pdf.

[316] A.G. Fraser et al., *Clinical evaluation of cardiovascular devices: principles, problems, and proposals for European regulatory reform*, European Heart Journal (2011:32) 1673-1686.

throughout the device's use, and then apply for it to be placed on the U.S. market.[317] Particularly in the 2000s, there was, according to Kruger and Kruger, a shift whereby most innovative medical devices were placed on the European market first. This was particularly favourable to small European companies, who account for a significant portion of the innovation in the medical devices sector.[318]

On the European side, several stakeholders have pointed out that one uncertainty in the transatlantic cooperation is the varying competences of the notified bodies in the EU. This creates a situation where unscrupulous actors may engage in forum-shopping and place devices on the European market even though they may not meet the requirements. This is something which may undermine the legitimacy of the entire system. Confidence and competence, with respect to both the FDA and the notified bodies, represent an uncertainty that may be disadvantageous to transatlantic trade.

A further aspect in this regard is data protection rules. In this regard, data protection refers not to personal integrity, but to the protection of business secrets and know-how. Companies that submit extensive test data to agencies and assessment bodies have a strong interest that such data does not become publicly accessible. Considering how dependent the medical devices sector is on innovation, the data protection aspect becomes an uncertainty for companies intending to sell their devices in both markets. Another barrier to trade highlighted by many stakeholders is the dual requirements on the control of quality management systems. This is also one of the areas of cooperation that has been prioritised by the Commission.

A problem highlighted by one company concerns software upgrades to information systems that are classified as medical devices in the EU and the U.S. In both regulatory frameworks, such updates might result in the manufacturer of the information system once again having to apply for authorisation/approval to market the device in question. According to the company, neither of the regulatory frameworks sufficiently takes into account the fact that medical IT devices depend on continuous updates to be innovative and reliable.

Standardisation

The medical devices sector is the subject of international standardisation that is used on both sides of the Atlantic, but there is naturally scope for increased international standardisation.

An uncertainty raised by one company is the varying degree of competence at European notified bodies to assess the application of standards. One example given by a manufacturer whose device had been authorised for sale on the European market and then made plans to sell on the U.S. market. The company examined the notified body's report and found that the device had been authorised for sale on the European market, even though the standard applied did not correspond in all respects to the Medical Devices Directive's requirements for quality management systems. Our assessment is that confidence in the control bodies can be a source of uncertainty, particularly as it is a problem raised by various stakeholders.[319] It

[317] Kramer et al. uses the example of a distal protection system for coronary-artery interventions. Such a system was certified for marketing in the EU on the basis of less extensive clinical data than in the U.S., where the device was only approved by the FDA several years later, after a major clinical trial.
[318] The Business of Healthcare innovation, p. 444.
[319] COM(2012) 542 final, p. 7; National Board of Trade, Ref no 2013/01832-35; National Board of Trade, Ref no 2013/01832-36.

should, however, be mentioned that this aspect need not only be ascribed to the notified bodies since the FDA has also been criticised for lack of impartiality.[320]

Another uncertainty mentioned is that the use of global standards places higher demands on transparency in the standardisation process to ensure that the standard corresponds to all regulatory requirements. If there are deviations, the standard should make it apparent not only which regulations it corresponds to, but also which requirements are *not* met if the standard is followed.

Product supervision

One potential barrier that has not been adressed is the lack of a common format for incident reporting. There is currently a global exchange of reported information, but no common reporting format.

Traceability

Common provisions for UDI systems are the subject of discussion at the global level within IMDRF[321] and have also been identified by several major industry associations as an aspect of medical device regulation in which the EU and the U.S. should cooperate.[322] The issue has also been raised by the Commission as a prioritised area of cooperation.

A risk raised by one consultancy firm in contact with the National Board of Trade is that the allocation of UDI codes in the U.S. is done by private companies. The risk, according to the firm, is that the actors that control this allocation can get into a position in which they are able to use their position to apply unfair conditions or prices. This could be problematic, especially if one of these actors were also active in the medical devices market. However, it should be emphasised that this description can be questioned because the companies that allocate UDI codes are accredited by the FDA. What may create uncertainty, on the other hand, are the conditions for accreditation.[323]

Other

Besides the requirements associated with the devices, the main technical regulations, there may also be other regulation that can affect the transatlantic trade in medical devices. Among others, there are requirements outside the primarily applicable law, such as restrictions on the use of certain hazardous materials and substances,[324] which may mean that some devices manufactured in the U.S. are not acceptable on the European market and vice versa. Different rules on producer responsibility for waste from medical devices may also disrupt

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[320] See e.g.: *Competitiveness and regulation: The FDA and the future of America's biomedical industry*, p. 5.

[321] See among others: IMDRF, *Roadmap for Implementation of UDI System*, 2012. Available at: http://www.imdrf.org/docs/imdrf/final/work-items/imdrf-wi-120923-presentation-udi.pdf; Global Harmonisation Task Force (GHTF) SC UDI Ad Hoc Working Group, *Unique Device Identification (UDI) System for Medical Devices*, 2011. Available at: http://www.ghtf.org/documents/ahwg/AHWG-UDIN2R3.pdf.

[322] Joint EU-US Industry Contribution to EU and US call for input on opportunities to promote greater regulatory compatibility in the medical devices sector**:** http://www.medicalimaging.org/wp-content/uploads/2013/04/FINAL-Joint-EU-and-US-Industry-Contribution-for-TTIP-meeting-10-April-20-.pdf.

[323] See e.g.: United States Trade Representative, *2013 Report on Technical Barriers to Trade*, 2013, p. 62. Available at: http://www.ustr.gov/about-us/press-office/reports-and-publications/2013/TBT-report.

[324] See e.g.: Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

transatlantic trade in medical devices.[325] Electrical safety can affect the opportunity to sell medical devices. Within the EU, there is harmonisation,[326] whereas in the U.S. different electrical safety requirements may be applicable at state level.[327]

On both sides of the Atlantic, cross-border trade is affected by public intervention in the provision of healthcare services. This means that public investment in medical devices can govern which devices are purchased, possibly leading to preferences in favour of domestic manufacturers. It might also mean the exclusion of certain manufacturers and distributors from procurement procedures if they do not, for example, meet demands for profitability,[328] something which particularly affects smaller companies.

6.6.3 Cooperative forms

Based on the uncertainties identified in the previous section, the National Board of Trade below outlines possible regulatory cooperation on medical devices.

Classification

Harmonisation of risk classes appears unlikely in the context of the TTIP negotiations, particularly since the Commission has recently proposed two new Regulations that are based on the existing classification system in the EU. However, cooperation should be possible in the form of increased information exchange between competent authorities, which could then perhaps produce information material to clarify the control procedures which a given device must undergo to gain access to both markets.

Pre-market controls

The similar performance and safety requirements of the EU and the U.S. constitute a good basis for cooperation through mutual recognition of test data and test reports. This is especially true since the testing of both medium-risk and high-risk devices is performed by third-party bodies in the EU and can be performed by third-party bodies in the U.S. Mutual recognition of test data need not mean that either side has to ease the substantive requirements for authorisation/approval, but does on the other hand open up an opportunity for agreement on which data manufacturers can use for market access (a “one-stop-shop” for conformity assessment). In this context, it is important to point out that the Commission has proposed a common application format as a basis for cooperation on market authorisation.

The Board's opinion, therefore, is that there is broad support from various actors to raise the requirements on the notified bodies within the EU, as the Commission has proposed in the new Regulation proposals. A consultancy firm with which the Board has been in contact proposed that the EU should go a step further and allow the notified bodies to perform the testing of the devices, while the national competent authorities issue the marketing authorisation. This presupposes, however, that there is confidence in the parties' respective assessment bodies. In this respect, it may be of interest to discuss what the least common

[325] See e.g.: Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE).
[326] Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits.
[327] The Commission, DG Trade, *Non-Tariff Measures in EU-US Trade and Investment – An economic analysis*, 2010, p. 165.
[328] The Commission, *Non-Tariff Measures in EU-US Trade and Investment – An economic analysis*, pp. 165-166.

requirements and competence standards are for such bodies, preferably on the basis of international standards.

For the testing and verification of high-risk devices, there is potential for information exchange between the advisory committee that assesses certain high-risk devices in the U.S. system and the expert committee proposed by the Commission for work on the new European regulatory framework. However, cooperation of this kind must be combined with data protection provisions that safeguard against the uncontrolled dissemination of know-how. Cooperation on assessments of quality management systems has been identified by both of the negotiating parties as well as industry associations and is therefore not discussed further here.

Standardisation
The overarching systematic problems of the respective negotiating parties' differing standardisation policies are difficult to resolve. However, there is considerable scope for a greater exchange of information about which standards are accepted in their respective jurisdictions. In many cases, international standards are accepted on both sides of the Atlantic, and this should make it possible to establish a procedure for drafting lists of those standards which both parties accept in market surveillance for medical devices. However, standardisation cooperation should also result in procedures for the acceptance of common standards, especially procedures that follow what may become guiding principles witin the IMDRF.

Product supervision
A common format for incident reporting could facilitate transatlantic trade and is a relatively uncontroversial negotiating point, especially since the issue is on IMDRF's agenda. Common incident reporting can be combined with enhanced information exchange on incidents. This can create a better basis for assessing safety in the use of medical devices.

Traceability
The parties' cooperation on UDI is uncontroversial, but the question is how UDI will be harmonised in practice. In the U.S., UDI codes are allocated by accredited bodies. Given that the U.S. introduced the system relatively recently, it is likely that it will take the initiative and advocate such a system as a starting point in the negotiations. Consideration must also be given to the discussions on global UDI harmonisation undertaken by IMDRF.

Other
Besides regulatory cooperation on technical trade issues, it should be considered whether there is reason to discuss potential non-tariff barriers that may arise due to public listing, pricing or reimbursement of medical devices. In that case, guidance may be derived from the FTAs that the EU has with South Korea and Singapore.

6.6.3.1 **Conclusions**

The Board's conclusion is that the transatlantic trade in medical devices is currently effective, but that there is still scope to increase regulatory cooperation between the EU and the U.S. The Board's view is that a transatlantic regulatory cooperation could generate benefits to society for both contracting parties through the greater availability of innovative medical devices for patients. The Board's assessment is that the medical devices sector is receptive to transatlantic regulatory cooperation because the devices in question are covered by similar requirements in the EU and the U.S.

As regards the Commission's priorities (common provisions for quality management systems, exchange of test data, common application formats, common UDI rules and common lists of harmonised standards), the Board sees no barriers to supporting those initiatives from the perspective of specific Swedish priorities.

Transatlantic regulatory cooperation on medical devices could potentially affect Swedish requirements for labelling and use instructions to be written in Swedish.[329] If so, the extent of the interest in maintaining such requirements should be considered. Otherwise, it may be concluded that Swedish interests in general should coincide with those of the Commission, to the extent that there is limited scope for EU Member States to adopt provisions on medical devices.

In the Board's assessment, the starting point for regulatory cooperation on medical devices in TTIP, as well as in the EU-South Korea and EU-Singapore free trade agreements, should be global cooperation models. For medical devices, the parties should advocate IMDRF as a primary forum for future global cooperation.

A successful cooperation on medical devices should also build upon existing regulatory cooperation between the negotiating parties. That cooperation should be deepened in several respects, particularly with regard to information exchange and transparency in order to create a better understanding of the regulatory frameworks and to provide a common foundation for cooperation. One problem in this regard may be that there is no natural counterpart to the FDA as market surveillance in the EU is decentralised. As part of the re-regulation of the European legislation, it has been discussed whether the European Medicines Agency or the Commission should assume the primary responsibility for administering the regulations. The Commission (DG SANCO) has proposed that it should assume the primary responsibility for monitoring the regulations. Regardless of which body is assigned this responsibility, consideration should be given to whether that body is to be the regulatory counterpart to the FDA with respect to regulatory cooperation.

The European regulatory framework for medical devices is currently undergoing its greatest overhaul in 20 years. After such an extensive legislative process, the Board notes that there may be a need to implement the new regulatory framework before introducing new regulatory changes.

The Board understands that there is strong support from Swedish stakeholders for the use of international standards to facilitate global trade. Regulatory cooperation between the EU and the U.S. on medical devices should not be an exception to this, especially since IMDRF also advocates the use of international standards.[330]

Finally, the Board's assessment is that a successful cooperation on medical devices presupposes that TTIP will not only lay the foundation for future regulatory cooperation, but that the parties will be able to reach an agreement that creates added value for actors operating on both the European and U.S. markets. The Board assesses there there is a scope to discuss and, if possible, harmonise technical regulations in order to eliminate certain dual burdens, such as registration requirements, incident reporting formats, testing requirements, etc.

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[329] AIMD Directive, Article 4(4); Medical Devices Directive, Article 4(4); IVD Directive, Article 4(4); Consolidated version of LVFS 2003:11 §4 p. 3.

[330] GHTF, *The Role of Standards in the Assessment of Medical Devices*, (GHTF/SG1/N044:2008) p. 7.

7. Conclusions

The work to prevent and eliminate technical barriers to trade between the EU and the U.S. constitutes a core issue in the current free trade agreement negotiations on the *Transatlantic Trade and Investment Partnership* (TTIP). As the markets are characterised by different regulatory models, both in terms of product regulations and agency structure, the challenge lies in finding the level of regulatory cooperation that provides a clear return in deeper market integration and maintained levels of regulatory protection, while at the same time not impairing the terms of trade with third countries.

Given the attributes that characterise the relationship between the EU and its internal market regulations and between the U.S. regulatory system and its federal and state regulations, both of which have their own structures and grant national and, to some extent, state applications, the view of the National Board of Trade is that the challenge crystallises in finding specific areas for regulatory cooperation rather than in finding one horizontal regulatory tool for all sectors. This is coupled with the complexity of greater, overarching policy areas, such as the environment, and that should be observed in the negotiations. One possible area for agreement on a horizontal level, and which may already be inferred from existing negotiating positions, is that mechanisms for rule transparency should be created between the markets in order to increase information and knowledge on existing and future regulation.

As regards more comprehensive regulatory cooperation in various sectors, the Board assesses that such work will demand:

- explicit channels for bilateral dialogue,
- forums where specific regulatory interests may find expression, and
- a process that enables an objective assessment of existing and future rules, with equal representation from both parties.

Besides this, there must be an explicit mandate[331] for the work that binds the parties to respect concluded agreements and a system for dispute settlement. The work must also be able to take into account and evaluate regulatory impact. This is especially important in areas that currently lack uniformity at the Member State level in the EU and where the U.S. regulatory structure allows differences at the state level.

With regard to the objective of creating regulatory coherence within sectors, the Board foresees several factors being significant for successful regulatory cooperation. The first is the *existence of equivalent regulatory agencies.* Transatlantic barriers to trade consist much of ignorance of existing regulations and how they are applied. The more complex the agency structure is within a sector, the more difficult it is to accomplish effective dialogue between the parties. In the area of chemicals, where it is not likely that the parties will come to an agreement on harmonised regulatory frameworks, it is clear, however, that the dialogue between ECHA[332] (the EU) and the EPA[333] (the U.S.) has led to increased knowledge of the regulations between the markets.

[331] One forum where it has been possible to reach agreement on *Common Regulatory Objectives* (CRO) in limited areas is UNECE WP.6 that has used the International Model for Technical Harmonisation. However, the weakness of the system is that it is not legally binding on any party.See: http://www.unece.org/fileadmin/DAM/trade/wp6/Recommendations/Rec_L.pdf.

[332] The European Chemicals Agency.

[333] The Environmental Protection Agency.

As regards the work to advance the prevention of new, and elimination of existing, technical barriers to trade, the core lies in *knowledge of regulatory equivalence* with respect to the level of protection (health, consumer protection, national security, etc.) that the markets want to achieve. If it were possible to express, in scientific terms, the level to be achieved and the methods used to achieve it (market surveillance, testing and control requirements, etc.), it would probably also be easier to determine whether individual regulations or regulatorysystems are to be considered equivalent and can be mutually recognised. The problem is that most areas lack such information on regulatory comparability. In areas where it is possible to determine the level (e.g. for certain vehicle requirements), there is naturally also a lower threshold for the rapid progress of regulatory cooperation. The same reasoning should be capable of being applied to overarching (horizontal) systems, such as standardisation in the EU and the U.S. The WTO Agreement on Technical Barriers to Trade (the TBT Agreement) does not define an international standardising body or an international standard. If the parties, especially for future regulation, could agree on what common regulations should advocate in a specific area, and what a standard should fulfil – consensus might be reached if *a common procedure for the acceptance of regulations and standards were to be created*, even though the structures of the parties' regulatory organisations are fundamentally different. However, besides a great political will, this demands joint forums with equal representation from both sides, a process with objective, scientific methods and a humble attitude towards international commitments and existing global rules that facilitate free trade.

A further element that should be considered in the choice of regulatory tools is *other policies.* Few products are covered only by functional requirements or technical performance requirements. Product rules for ICT, automotive, etc. are also affected by overarching bodies of legislation on, e.g. the environment and sustainability. These policy areas are handled differently in the EU and the U.S. and within different sectors. The recommendation here is to consider the interaction of various regulatory frameworks before establishing whether or not regulations are to be regarded as equivalent, and whether it is feasible to agree on, or work towards, other overreaching obejctives.

As current EU regulations for goods in several areas grant *freedom in implementation at the Member State level* (national regulation), it is important that the EU is able to agree internally on the objectives that are to be applicable before cementing a certain line in the negotiations. For the Member States, this means that they should be well informed about any special national priorities in different sectors during the negotiations.

7.1 Sectors

General

Based on its sector analysis, the National Board of Trade is able to identify a certain imbalance as regards the approximation of the EU and the U.S. towards international regulations. Although it is clear that both parties can benefit from the distinctive profile of its own regulatory system (especially the U.S. through its decentralised standardisation system), there are indications that the EU's links to international regulations, together with other important trading parties such as South Korea, Canada, China, India (e.g. in chemicals, automotive), could provide a certain negotiating advantage for the EU in that the U.S. regulatory model lacks an equally broad global recognition on different levels.

Automotives

Regulatory approximation between the EU and the U.S. in line with the industry's proposal on the mutual acceptance of rules is feasible. The proposal is based on the fact that a great number of, though not all, vehicle rules in the EU and the U.S. being considered equivalent from a traffic safety perspective. However, some work must be invested in finding the right method for the mutual acceptance of vehicle rules between the markets. The way forward should be based on rule comparison linked to an analysis of the effects of these regulations. If the rules can be considered equivalent, they should be embraced by mutual recognition by the EU and the U.S.

One approach would be within the negotiations to address regulatory areas in clusters, such as active and passive safety, in order to bring greater coherence to the overarching regulatory objectives. Based on the study cluster approximation seem applicable to *existing rules* with parties working towards mutual recognition, but would be a more difficult method *for new regulations*.

In addition to this, the effect of other overarching policy areas (e.g. the environment), as well as areas with existing opportunities for special national implementation, must be taken into account in the negotiations on vehicle regulations.

However, the EU and the U.S. should work together towards international rules, *Global Technical Regulations* (GTR) and *Whole Vehicle Type Approval* (WVTA), because such work constitutes a sustainable model in the global perspective.

Opinion is divided regarding the benefits of TTIP to the Swedish automotive industry. This is linked to the investments made by various actors to adapt their activities to U.S. rules. In the long run however stakeholders interviewed foresee many benefits in greater regulatory coherency.

ICT

The analysis of the ICT sector has focused on industrial ICT products. Areas such as information security, the internet, services, etc. are not dealt with, and thus a large part of the ICT sector falls outside the analysis. The industry representatives that the Board has been in contact with in Sweden express roughly the same positions as those of the European interest organisations, but also largely those of the European Commission[334]. It has been difficult to identify Swedish interests that differ from the EU level.

The main barriers to trade that have been highlighted are questions of transparency, conformity assessment procedures and standardisation issues in general. Other major challenges identified in the sector are horizontal, such as regulation of electrical safety and the environment.

There are relatively low levels of regulatory differences between the legislation of the EU and the U.S. In practice, however, companies perceive the differences as relatively great in some areas, such as conformity assessment procedures and electrical safety (OSHA[335]). There is an MRA between the EU and the U.S. which is relevant to the sector, but which does not function fully satisfactorily in terms of conformity assessment procedures.

Industry believes that future areas for regulatory cooperation that should be included within the scope of TTIP are, e.g. the environment, conflict minerals and nanomaterials.

[334] Hereafter referred to as *the Commission.*

[335] U.S. Occupational Safety and Health Administration regulations.

Government agencies and industry have expressed some concern about future adjustments in terms of the legal framework of ICT in the EU.

Mutual recognition of testing and certification or harmonisation of standards appear to be the most appropriate measures to reduce current barriers in the sector. One solution for increased transparency might be to compile agency requirements and make them available in an easily accessible way. Despite the challenges, the MRA mentioned is still an important cooperation at a deeper regulatory level to work for and accumulate experience of the recognition of conformity assessment procedures, as well as the results of this. This is something that future cooperation should be able to take advantage of. A cooperation body between the EU and the U.S. is advocated by both the Commission and industry in the sector. This body would, for example, be able to perform detailed work on standards or study conformity assessment procedures.

The innovative, global nature of ICT products requires a global regulatory environment using internationally approved rules and standards. The industry believes that the negotiations between the EU and the U.S. can have a positive effect on global developments and establish a number of guiding principles for trade in the ICT sector. The cooperative forms that might constitute a basis for the work under TTIP include international initiatives, such as the work of the ITA Committee[336] or the UNECE[337], where regulatory objectives and various transparency initiatives for the sector have been developed, e.g. a list of approval procedures for strategically important products.

Chemicals

With regard to the division of responsibilities for chemicals and the risks they entail, there are fundamental differences between the regulatory systems of the EU and U.S. In the EU, REACH[338] places responsibility on manufacturers and importers. If they cannot present data for the chemicals they want to manufacture or handle, they may not enter the market. If there is evidence that there is a risk, albeit scientifically uncertain, a preventive measure can be justified in light of the precautionary principle. In the U.S., the division of responsibility is the opposite. In order to restrict chemicals. it is the responsibility of the *Environmental Protection Agency* (EPA) to present data that demonstrates an unreasonable risk in order to restrict chemicals. Until this can be done, the chemical is free to be placed on the market. In order to require further information from companies, the EPA must demonstrate the existence of an unreasonable risk. Therefore, the EPA must itself generate data if companies are not willing to share the data they hold.

Neither the EU, the U.S. nor the industry are seeking a harmonised chemicals legislation, and to promote this would therefore appear unnecessary. It appears instead expedient to work to achieve the lowest levels of regulatory cooperation, i.e. information exchange/rule transparency and the observation of overarching international commitments. There are in some cases already established systems on which to build, such the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) and the *Mutual Acceptance of Data* (MAD) for the production and exchange of data. The EU should pursue the full implementation of the GHS by the U.S.

Several stakeholders have expressed concerns that TTIP might lead to a weakening of chemicals regulation and that it might hinder rule development and innovation. It is

[336] Ministerial Declaration on Trade in Information Technology Products (ITA).
[337] United Nations Economic Commission for Europe (UNECE).
[338] Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), see Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006.

important that the further process highlights the wording presented and investigates the actual meaning, e.g. a consultation procedure in conjunction with the drafting of new rules.

The industry has expressed concerns regarding data exchange as well as the desire for continued acceptance of its ownership of the data it has produced. This is a central question. Nevertheless, it is important to keep in mind that this view is not necessarily shared by SMEs, which have weaker opportunities to generate data.

Pharmaceuticals

The conditions for increased cooperation between the EU and the U.S. are relatively good in the pharmaceuticals sector. Global cooperation on pharmaceuticals (e.g. ICH[339]) and the fact that pharmaceuticals regulation in the EU and the U.S. ultimately aims to ensure that drugs are safe and efficacious, mean that there is a generally well-established consensus on how pharmaceuticals should be regulated. The regulation structures are thus similar on both sides of the Atlantic, something which simplifies the possibility of increased cooperation under TTIP.

The pharmaceuticals sector is largely characterised by being production heavy and involving different types of legislation; substantive requirements placed on pharmaceuticals, formalised requirements on authorisation/approval procedures and intellectual property considerations. In addition, there is a strong element of public control and steering. In the EU, this particularly applies to the Member States' right to have control over their national healthcare systems, including rules on pricing and the purchasing of drugs.

In some areas, cooperation is already underway between the drug authorities, the *European Medicines Agency* (EMA) and the *U.S. Food and Drug Administration* (FDA). What has previously prevented deeper cooperation may be attributed to the EU's fragmented treatment of pharmaceuticals among the Member States. The Commission has taken measures to harmonise the pharmaceuticals sector and, together with the EMA, create unison guidelines and promote transparency.

From a Swedish perspective, the measures proposed by the Commission can be generally described as positive. Many actors welcome measures to increase transparency and coherence between the EU and the U.S. Companies have stressed the importance of safeguarding intellectual property interests in TTIP. The Board's assessment is that the conditions for mutual recognition in areas that have been the subject of international harmonisation are particularly good. In areas which lack initial harmonisation measures, TTIP should promote a development towards the production of common guidelines between the EU and the U.S. This type of approximation creates the conditions for mutual recognition in the future.

Medical devises

The priorities concern common provisions for quality management systems, exchange of test data, coordinated application formats, coordinated rules for *Unique Device Identification* (UDI) and common lists of harmonised standards. Swedish priorities should essentially coincide with EU priorities because the scope for national regulation is very limited for medical devices. One special Swedish requirement that exists is that for labelling and instruction manuals to be in Swedish. To the extent that other Member States have

[339] The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

corresponding requirements, this is an aspect that may need to be adressed in the negotiations.

A successful transatlantic cooperation on medical devices should be based on international regulatory cooperation, primarily that of the *International Medical Device Regulators Forum* (IMDRF). In addition, the agreement should result in added value that favours transatlantic trade, e.g. through the elimination of duplicated regulatory burdens, such as registration requirements, incident reporting formats, testing requirements, etc.

The European regulatory framework for medical devices is currently undergoing its greatest overhaul in 20 years. After such an extensive legislative process, some time may need to pass before new regulatory changes can become possible. In the development of new regulations, the Board considers it important for the competence of, and confidence in, the notified bodies to be strengthened.

List of this report's overall conclusions regarding deeper cooperation between the EU and the U.S. in the TBT area

Conclusion 1

- It is not possible to implement *one* model of horizontal mechanisms that may apply to all the sector areas of TTIP – each sector is unique and requires its own solutions

Conclusion 2

- Horizontal mechanisms can, however, be introduced for transparency and comitology – e.g. notifications of draft technical regulations and committees

Conclusion 3

- It is important to have a parallelism in the cooperation, with an equal representation on both sides and any assessments made being based on scientific approaches

Conclusion 4

- Confidence-building measures on a deep regulatory level should be encouraged

Conclusion 5

- It is important to identify EU and U.S. agencies that can be each side's counterpart as "sister agencies" – this centralisation in structure enables a decentralised approach for sectoral issues of deep complexity

Conclusion 6

- The question of standardisation is complex and requires flexible approaches

Conclusion 7

- Priority should be given to those areas where there is opportunity to achieve results in the short term and with limited resources – however, these measures must be based on and be linked to a long-term and structurally considered plan, perhaps in the context of updated TTIP agreements

Conclusion 8

- In areas where the rule differences are too great, long-term measures should be taken that will allow future regulation to be adapted in order to enable cooperation and avoid new barriers to trade

Conclusion 9

- Interaction with the multilateral trading system (WTO) must be given consideration – the possibility of successful results is dependent on the sustainability of solutions from an international perspective

Conclusion 10

- International harmonisation processes are very often the key to giving the best conditions for cooperation between the EU and the U.S.

Conclusion 11

- Awareness and knowledge with respect to the regulatory similarities and differences between the EU and the U.S. are decisive to the taking of the right measures

Conclusion 12

- Information and classification systems regarding; (a) regulatory coherence, (b) common requirement levels in sector areas enable an overview that is currently lacking

Conclusion 13

- Procedures for the enforcement of judgments and dispute settlement should be introduced to lend weight to the agreement. However, it is important that such wording does not curb the possibility of cooperation in politically sensitive areas

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