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Risks and Opportunities for Consumer Welfare Arising from the Transatlantic Trade and Investment Partnership (TTIP)



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Risks and Opportunities for Consumer Welfare Arising from the Transatlantic Trade and Investment Partnership (TTIP)

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Abbreviations

AFR	Americans for Financial Reform
AFME	Association for Financial Markets in Europe
AIM	European umbrella organisation of health mutuals and health insurance funds
AMS	Agricultural Marketing Service
AOEL	Assoziation ökologischer Lebensmittelhersteller (Association of Organic Food Producers)
B2B	Business-to-Business
BCFP	Bureau of Consumer Financial Protection
BDI	Bundesverband der Deutschen Industrie e.V. (Federation of German Industries)
BEUC	Bureau Européen des Unions de Consommateurs (European Consumer Organisation)
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Products)
BfDI	Bundesbeauftragte für den Datenschutz und die Informationsfreiheit (Federal Commissioner for Data Protection and Freedom of Information)
BfR	Bundesinstitut für Risikobewertung (Federal Institute for Risk Assessment)
BITKOM	Bundesverband Informationswirtschaft Telekommunikation und Neue Medien (German Association for Information Technology, Telecommunications and New Media)
BMG	Bundesministerium für Gesundheit (Federal Ministry of Health)
BMI	Bundesministerium des Inneren (Federal Ministry of the Interior)
BMJ	British Medical Journal
BMWi	Bundesministerium für Wirtschaft und Energie (Federal Ministry of the Economy and Energy)
BÖLW	Bund Ökologischer Lebensmittelwirtschaft (Association of the Organic Food Industry)
CDD	Center for Digital Democracy
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
DBV	Deutscher Bauernverband e.V. (German Farmers' Federation)
EBA	European Banking Authority
EFSA	European Food Safety Authority
EIOPA	European Insurance and Occupational Pensions Authority
EMA	European Medicines Agency
ESMA	European Securities and Markets Authority
ESFS	European System of Financial Supervisors
ESBR	European Systemic Risk Board
EU	European Union
EUDAMED	European Databank on Medical Devices
EUR	Euro
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration

FTC	Federal Trade Commission
GBE	Gesundheitsberichterstattung des Bundes (Federal Health Monitoring System)
GMO	Genetically modified organisms
GMP	Good Manufacturing Practice
HLWG	High Level Working Group on Jobs and Growth
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
INFOSAN	International Food Safety Authorities Network
ISDS	Investor-state dispute settlement
NMPF	National Milk Producers Federation
RASFF	Rapid Alert System for Food and Feed
SIFMA	Securities Industry and Financial Markets Association
SIIA	Software and Information Industry Association
TABC	Transatlantic Business Council
TACD	Transatlantic Consumer Dialogue
TATFAR	Transatlantic Taskforce on Antimicrobial Resistance
TTIP	Transatlantic Trade and Investment Partnership
TÜV	Technischer Überwachungsverein (Technical Inspection Association)
UN	United Nations
USITC	United States International Trade Commission
USPTO	United States Patent and Trademark Office
VFA	Verband forschender Arzneimittelhersteller e.V. (Association of Research-based Pharmaceutical Companies)
VZBV	Verbraucherzentrale Bundesverband e.V. (Federation of German Consumer Organisations)
WHO	World Health Organization
WTO	World Trade Organization

Preliminary Remarks and Summary

The economic policy agenda has in recent months been dominated by one issue: the negotiations on the Transatlantic Trade and Investment Partnership (TTIP) between the EU and the United States (hereafter: 'the Agreement'). What is special about TTIP is that it does not concern primarily the removal of tariff trade barriers (such as customs duties), but rather the reduction of non-tariff trade barriers by means of instruments of regulatory cooperation. Directly in the spotlight here are environmental, social and consumer standards. This also explains the broad public interest in the negotiations and the controversial debate between politicians, the business sector and representatives of civil society.

The aim of the present study is to analyse and evaluate the current state of the negotiations and the public debate on the Agreement with regard to its consumer-policy implications. To this end we develop an evaluatory framework that enables us to measure the effects of the relevant instruments for removing non-tariff trade barriers on the individual dimensions of consumer welfare in the following submarkets, which are of particular importance to consumers: (I) food and nutrition, (II) drugs and medical products, (III) data flows and data protection and (IV) financial services.

The key results of our research can be summarised in terms of six theses:

Thesis 1:

Transatlantic relations are characterised in a number of instances by fundamentally different regulatory philosophies, which preclude overall harmonisation or mutual recognition.

Thesis 2:

In some areas, however, there are also substantial similarities with regard to regulatory approaches that should not be overlooked and in which harmonisation or mutual recognition of standards would make sense.

Thesis 3:

There is enormous consumer-policy potential in intensified exchange of information between the EU and the United States. This should be tapped within the framework of regulatory cooperation.

Thesis 4:

The assumption that the level of consumer protection or regulatory approaches in the EU are fundamentally higher or better is not warranted.

Thesis 5:

In order to tap the potential of regulatory cooperation minimum requirements have to be met.

Thesis 6:

The TTIP negotiations have the potential to promote the interests of consumers. However, in order to realise this potential a change of mentality is needed in the conduct of the negotiations.

The present report appears within the framework of a foundation-wide focus on TTIP by the Friedrich-Ebert-Stiftung. The purpose is to analyse and discuss individual issues, conflicts and the global effects of TTIP at public events and expert discussions involving experts from politics, trade unions, the economy and civil society and in publications.

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1. Introduction

1.1 Background

In recent months, the negotiations on the Transatlantic Trade and Investment Partnership (TTIP) have dominated the economic-policy agenda between the European Union and the United States. Never before have the pros and cons of a free trade agreement been debated so intensively and with such controversy in the business sector and the political arena, as well as among the general public in Germany.

Two points of view are in contention here. On one hand, advocates of the Agreement point to its potential with regard to economic growth, new jobs and unburdening the economy of unnecessary costs and red tape by harmonising standards. The European Commission has declared that the Agreement is 'the most cost-beneficial economic growth programme imaginable' (European Commission 2013a: 3).

On the other hand, trade unions, NGOs, church representatives and even some business actors and associations criticise the non-transparent conduct of the negotiations, denounce the 'power of lobbyists' and warn of a 'new super fundamental right' and the 'selling out of Europe' (Hansen/Gala 2014; Piratenpartei 2014).

There are three main reasons why this agreement in particular is so controversial. First, the aim of the negotiations is not the removal of tariff trade barriers (such as customs duties), but above all the reduction of non-tariff trade barriers (such as market access regulations and product and production standards). These market access regulations and product and production standards can be protectionist in motivation. However, they can also express citizens' entirely legitimate national preferences and moral concepts, which should not be sacrificed one-sidedly to commercial interests.

Secondly, the Agreement is aimed not merely at achieving one-off results from the negotiations but at establishing institutions and instruments that will continue into the future to facilitate improved regulatory cooperation between the two economic areas. This aspect is often expressed under the term 'living agreement'.

Thirdly, the Agreement is extremely ambitious. Regulations are to be laid down not only for selected economic sectors, but for a large number of sectors that have repeatedly given rise to trade disputes between the EU and the United States in recent decades, ranging from food and agriculture, through medical products to data flows and financial services. This is also the reason why critics of the Agreement fear that the sheer multitude of topics will turn it into a kind of 'package deal', in the sense that the gains of one negotiating partner in one area will be 'bought' with concessions in another area, as a result of which fundamental labour, environmental and consumer protection standards will fall by the wayside.

1.2 Objective and research questions of the Study

The aim of this study is to analyse and evaluate the current state of negotiations on the Agreement – as far as it is possible to know – with regard to its implications for consumer policy. An analysis and evaluation of this kind is desirable for a number of reasons. First, in recent months consumer-policy issues have been well to the fore in the public debate on the Agreement. Examples include fears concerning chlorinated chickens, hormone-treated meat products and genetically modified organisms, which as a result of the Agreement could find their way into the European single market and thus undermine protection standards that European citizens regard as sensible and desirable.

Secondly, consumer-related aspects of the Agreement highlight fundamental issues concerning the potential of an intensified transatlantic economic partnership. If it is the case that the two sides are characterised by fundamentally different and thus incompatible regulatory philosophies – the ‘precautionary principle’ in the EU and what one might call the ‘reactionary principle’ in the United States – or that the level of consumer protection in the EU is fundamentally higher and the consumer protection regime more effective than in the United States, then from a consumer policy standpoint the basic question arises of whether the negotiations make any sense.

Thirdly, to date systematic scientific evaluations of the negotiations from a consumer protection perspective are lacking.

The aim of the present report therefore is to scrutinise the arguments concerning consumer protection brought to bear in public discussions and to place the public and expert debates on a firmer footing. For this purpose we shall establish an evaluatory framework from the consumer point of view and use it to examine four submarkets of particular importance for consumers.

Within the framework of our analysis of the Agreement the following issues will be addressed:

- What aspects have to be considered and, perhaps, weighed against one another in an evaluation of the opportunities and risks of the free trade agreement?
- What are the main similarities and differences with regard to the regulation of markets in the United States and the EU?
- What opportunities and dangers may result for consumer-policy standards and regulations from a European perspective?
- How can it be ensured in a Euro-Atlantic single market that meaningful standard-setting will continue to be enacted and adopted in the area of consumer protection by national and European institutions?

1.3 Method and Methodological Constraints

The present study is based, on one hand, on a review of the literature and, on the other, on expert interviews with key stakeholders from consumer protection, the economy and associations. The interviews – conducted in May and June 2014 – were necessary to obtain a deeper understanding of stakeholders’ positions. (A list of all interlocutors may be found in Appendix 1.)¹

In order to evaluate the state of the negotiations from a consumer-policy standpoint, in Section 2 we develop an evaluation matrix, with the help of which, in Section 3, we analyse four submarkets of particular importance from a consumer standpoint. The four submarkets are: food and nutrition, drugs and medical products, data flows and data protection, and financial services. In Section 4 we summarise the findings of our investigation and present some conclusions.

The following factors were decisive in selecting the four submarkets: (I) the political importance of the markets in the current public debate; (II) the real importance of the markets for consumers; and (III) the availability of information on the state of the negotiations.

The following methodological limitations have to be taken into account with regard to the present study:

- **Market coverage is incomplete:** Because of our limited resources only four submarkets could be examined within the framework of this study (see above). That is to say, other markets of particular importance for consumers – such as textiles, chemicals, cosmetics and public services – are not examined here.
- **There is no analysis of the consumer-policy potential of tariff reductions:** This study is limited to analysing the consumer-policy potential of reducing non-tariff trade barriers. The implications of reducing tariff trade

¹ The authors would like to thank the interview partners for their considerable help. They made a decisive contribution to our understanding of the standpoints of the various stakeholders.

barriers – namely customs duties – are beyond the scope of the study. For the sake of completeness, however, in Section 2.2.1 we look briefly at the theory related to instruments for reducing tariff trade barriers.

- **Structural aspects of the conduct of negotiations are not addressed:** Besides criticisms of the contents and possible consequences of the Agreement fault has also been found in the public debate with the manner in which the negotiations are being conducted. Secret negotiations, lack of transparency and one-sided attention to the interests of economic actors are key concerns. These issues are not the object of this study, however, and thus are only touched on.
- **Horizontal issues are largely ignored:** Besides the market-related issues highlighted by the Agreement there is currently considerable controversy concerning two ‘horizontal’ aspects: regulatory cooperation and investor protection by means of so-called ‘investor-state dispute settlement’ (ISDS). Although the first

issue is looked at in Section 4, we shall have nothing to say about ISDS. On one hand, treatment of the problems with ISDS is beyond the scope of this study; on the other hand, Pia Eberhardt has addressed this issue for the Friedrich-Ebert-Stiftung within the framework of her study ‘Investitionsschutz am Scheideweg: TTIP und die Zukunft des globalen Investitionsrechts’ (Investment protection at the crossroads: TTIP and the future of global investment law) (Eberhardt 2014).

- **Insufficient knowledge of the current state of negotiations:** In the areas in which official documents on the state of the negotiations are available this study refers to them. However, this is the case in only a few instances. In order nevertheless to be able to evaluate the negotiations and their possible consumer-policy implications our analysis is based on ‘leaked’ documents or refers to aspects cited in the public discussion. Of course we had no access whatsoever to official US government documents.

2. Categorisation and Evaluatory Framework

The aim of this section is to summarise the key features of the Agreement and the aims of the negotiations, present the basic instruments for reducing tariff and non-tariff trade barriers and address the relevant problems from a consumer perspective. Furthermore, we develop an evaluatory framework for the negotiations from a consumer standpoint. We need to categorise the negotiations and the evaluatory framework in order to be able to analyse the submarkets in Section 3.

2.1 Aims of the Agreement and Course of the Negotiations

The Transatlantic Trade and Investment Partnership (TTIP) is a free trade agreement that the EU and the United States have been negotiating since July 2013. The negotiations on TTIP got under way as early as November 2011 with the establishment of a joint High Level Working Group on Jobs and Growth, comprising experts from the US government and the European Commission. The task of the High Level Working Group was to identify options for further deepening trade relations between the EU and the United States and to evaluate the potential of a free trade initiative. In February 2013 the High Level Working Group presented its final report, in which it came out clearly in favour of more intensive cooperation between the two economies and thus officially set the negotiations in motion.

Four months later, in June 2013, the EU Council of Ministers unanimously approved the mandate for conducting the negotiations ('Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of

America'), whose first round commenced in July 2013. Since then the negotiators of the two sides have met on seven occasions.

Specifically, the mandate of 17 June 2013 is to pursue the objective of 'increas[ing] trade and investment between the EU and the US by realising the untapped potential of a truly transatlantic market place ... through increased market access and greater regulatory compatibility' (European Commission 2013b: 4).

The negotiators expect welfare gains for consumers from a transatlantic market, to be achieved primarily by means of the following measures (European Commission 2014g: 1):

- facilitating market access by removing customs duties on goods and certain restrictions on services, as well as providing better access to public procurement markets and making it easier to invest;
- improving regulatory coherence and cooperation by dismantling unnecessary regulatory barriers;
- improved cooperation when it comes to setting international standards.

According to the mandate, sustainable development is also to be promoted and a high level of environmental, labour and consumer protection is to be ensured (European Commission 2013b: 4).

Furthermore, the mandate contains a section on facilitating investment opportunities and improved investment protection (ISDS). In this respect the main aim of the chief negotiators is to ensure that investors are not discriminated against in favour of domestic producers and that their investments are protected. Although these aspects are not the object of the present analysis (see Section 1.3) the discussion will be summarised briefly because reference is sometimes made to it in the analysis of the selected submarkets.

With regard to ISDS, critics argue that it will give investors and large companies comprehensive rights to file actions, enabling them to sue states before private international courts if state regulations lead to *expropriation-like intervention*, for example, by threatening a company's property rights and anticipated profits (Eberhardt 2014: 4). The fear is that this would give investors disproportionate rights, undermine states' sovereignty to regulate and ultimately lead to a 'regulatory chill', with governments not even implementing certain regulatory measures in the first place in order to avoid tax-payers being saddled with the bill for compensation for damages (Matthes 2014: 3).

On the other hand, advocates of TTIP argue that the negotiations offer a good, high-profile opportunity to modernise the outdated structures of investor-state dispute settlement procedures and establish an international 'gold standard' (BDI 2014). This is particularly necessary because the earnings of companies from many EU member states from foreign direct investment are almost double their earnings from exports. At the same time, however, there is no generally applicable multilateral regulatory framework for market access and investment protection, for example, by analogy with the WTO provisions on trade of goods and services (BDI 2014: 6, 17).

Looked at from a European negotiating standpoint it also seems problematic to entirely exclude regulations on investor-state arbitration from the TTIP negotiations if, at the same time, such regulations are to be implemented with economies such as China (BDI 2014: 25). Nevertheless, the German government has now distanced itself from including an investment-protection chapter and has made this a condition of Germany's assent to the Agreement (Gabriel 2014: 3).

2.2 Instruments for Removing Trade Barriers

In order to achieve the ambitious aims of the negotiating mandate and thus to create the world's biggest liberalised economic area, the negotiating partners have various instruments for removing

tariff trade and non-tariff trade barriers at their disposal. These instruments are not only characterised by their scope of application and economic consequences, but also have various consumer-policy implications.

2.2.1 Instruments for Removing Tariff Trade Barriers

With regard to removing *tariff* trade barriers the European Commission's negotiating mandate focuses above all on eliminating customs duties in bilateral trade. These trade barriers are supposed to be largely abolished by the time the Agreement comes into force and the remainder abolished gradually thereafter (European Commission 2013b: 5). Derogations from this will include a number of sensitive areas, such as beef, poultry and pork, as well as sugar and some varieties of vegetable, in which trade will continue to be regulated by customs duties (DBV 2014: 1).

Because the level of customs duties in transatlantic trade is already low – with an average customs rate of 4 per cent for industrial goods and 13.9 per cent for agricultural goods in the EU and corresponding rates of 3.3 per cent and 5 per cent in the United States (Mildner/Schmucker 2013: 2) – the trade and welfare effects arising from removal are likely to be modest (Felbermayr et al. 2013: 24). However, this is put into perspective by the fact that, besides the relatively low average customs duties, there are a number of peak tariffs – for example, on agriculture, textiles, clothing, shoes, chemicals and medical devices (Mildner/Schmucker 2013: 2) – and that, with a daily trade volume of 2 billion euros, even small customs duty reductions could have a substantial effect overall.

For consumers the removal of customs duties is always significant if companies pass on reduced costs in the form of price cuts. Apart from that, the removal of customs duties has the potential to increase the range of products if new companies come to engage in transatlantic trade as a result of the elimination of customs obligations. Welfare effects of the kind that are important to consumers only kick in, however, if the relevant markets are competitive.

2.2.2 Instruments for Removing Non-Tariff Trade Barriers

The removal of *non-tariff* trade barriers constitutes the second significant pillar of negotiations on the transatlantic free trade initiative. According to the negotiating mandate, unnecessary differences in regional standards and regulations are to be abolished 'by means of effective and efficient mechanisms' and an 'ambitious level of regulatory compatibility for goods and services' achieved (European Commission 2013b: 11).

The assumption here is that, on both sides of the Atlantic, laws and provisions apply on the protection of health, general and financial safety and security, the environment, consumers and other collective goods that have broadly the same aim but are regulated differently (European Commission 2014g: 1f).

These differences lead, as far as the negotiators are concerned, to higher costs because companies that want to sell their goods in both economies have to comply with the regulations in the export market as well as those at home. Specifically, the following implications for trade arise from the parallel regulatory structures (European Commission 2013a: 8f):

- Differing provisions can mean that a product is not even allowed to be sold in the export market.
- Differing standards can mean that separate production lines have to be set up for the export market.
- Differing regulatory frameworks and approaches to certification can mean that duplicate testing is required, thus leading to twice the financial outlay.

This, in turn, has direct effects on consumer welfare because certain products and services from abroad are available on the domestic market either only at a higher price or not at all.

The expectation is that no less than 80 per cent of the potential gains from TTIP would be generated by the removal of non-tariff trade barriers, the liberalisation of trade in services and the opening up of public procurement markets (Center for Economic Policy Research 2013: VII). On

this view the current regulatory differences between the two economies amount to a tariff equivalent of between 10 and 20 per cent. This not only affects the competitiveness of products in transatlantic trade, but is usually borne directly by consumers through higher end prices (Karmakar 2013: 2).

The negotiators thus emphasise that not only could a general boost to growth be expected from the removal of non-tariff trade barriers but consumers could benefit directly from a wider range of products and falling costs. Studies commissioned by the European Commission assert that the European economy could grow by 119 billion euros by 2027 due to the abolition of tariff and non-tariff trade barriers, which is the equivalent of an income boost of 545 euros for every European family (Center for Economic Policy Research 2013: VII). Furthermore, a rise in consumers' real incomes is also on the cards because the elimination of customs duties and increasing transatlantic competition could result in lower prices for consumer products. In addition, consumers could benefit from an increased selection of products and new products from the other economic area.

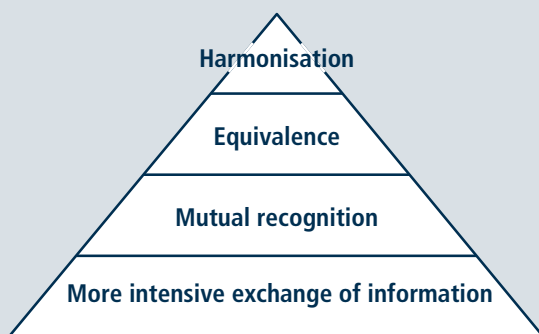
These forecasts have been called into question, however, and need to be treated cautiously. First, it is disputed whether companies would really pass on all the customs duty and production cost savings to their customers through lower end prices and whether European consumers would in fact consider the expanded selection of products as a welfare gain. Secondly, it has been pointed out that the forecasts assume an almost total abolition of tariff and non-tariff trade barriers, which is improbable (Stephan 2013). Thirdly, the abolition of non-tariff trade barriers would involve the infringement of national regulations on product and food safety or consumer and environmental protection. That means that potential cost savings for consumers from the abolition of non-tariff trade barriers could give rise to costs or other non-financial disadvantages elsewhere, which the forecasts do not take into account (Salavati 2014).

How strongly the removal of non-tariff trade barriers would ultimately affect national regulations on consumer protection would depend largely on which instruments of regulatory cooperation are eventually chosen. The options range from intensive exchange of information between the negotiating partners, on one hand, to total harmonisation of standards, on the other. The different instruments are presented in Figure 1. The higher up in the pyramid an instrument is placed, the higher its level of intervention.

In the next subsections we review the various instruments for removing non-tariff trade barriers (Sections 2.2.2.1 to 2.2.2.4) and address their implications for consumers (Section 2.2.2.5).

Figure 1:

Overview of instruments for removing non-tariff trade barriers



Source: Authors' graphic.

2.2.2.1 Exchange of Information

The weakest form of regulatory cooperation would be a structured exchange of information between the negotiating parties, as well as improved cooperation between the relevant regulatory authorities at the sectoral and horizontal levels.

Through regular and timely consultations on standard setting and regulation the respective experiences and expertise of the other negotiating party could be drawn upon to contribute to the development of new standards. This not only supports the idea of 'mutual learning' but can also counteract the formation of contrary or diverging parallel systems.

Closer cooperation between the two parties would also make it possible to identify systemic risks in the area of international consumer protection earlier and more effectively – for example, through the setting up of special early warning systems – and to introduce effective counter-measures.

2.2.2.2 Mutual Recognition

Mutual recognition goes a decisive step further and takes two forms. On one hand, within the framework of mutual recognition the differing standards and rules of the negotiating partner – besides one's own regulations – can be recognised as permissible. With regard to international trade this means that products of companies subject to the regulatory frameworks of an exporting country are automatically permitted to be offered for sale in the importing country (Veggeland/Elvestad 2004: 8f).

On the other hand, mutual recognition can apply to conformity assessment procedures. In this instance, the negotiating parties recognise one another's assessment procedures as equivalent. That does not mean that different standards are recognised as equivalent. Rather the exporting country – for example, institutions in the United States – scrutinises conformity with the regulations of the importing country (for example, the EU). Companies thus still have to satisfy the provisions of two different sets of standards. However, by this means the costs of duplicate checking are saved because one relies on the certification institutions of the counter-party (Veggeland/Elvestad 2004: 8f).

2.2.2.3 Equivalence

The principle of equivalence represents a further augmentation of the abolition of non-tariff trade barriers. In this case it is assumed that the same objective – for example, with regard to consumer safety or protection – can be achieved by different means. In other words, one recognises that there are different ways of achieving a goal and regards them as equivalent (Veggeland/Elvestad 2004: 8).

An example of this is the Eco-equivalency Agreement between the EU and the United States that came into force in 2012. According to this agreement products can be marketed in both markets as biological products almost without restriction, regardless of whether they were produced and certified in accordance with the EU Eco-Regulation or the National Organic Program (NOP) (AOEL 2012).

Equivalence is thus another way of maintaining national regulatory structures, while removing trade barriers at the same time.

2.2.2.4 Harmonisation

The most far-reaching form of abolition of non-tariff trade barriers is harmonisation. In this instance the negotiating parties agree on a single valid standard, which henceforth applies in both economies.

Harmonisation entails the complete abolition of non-tariff trade barriers. However, implementation is highly complex because two or more sets of regulations have to be condensed into one against the background of differing protection and regulatory standards (Veggeland/Elvestad 2004: 7).

2.2.2.5 Examination of the Instruments for Removing Non-tariff Trade Barriers between the EU and the United States

The negotiators emphasise that the negotiations on TTIP are not about a race to the bottom on both sides of the Atlantic to bring down standards or to force harmonisation to the lowest common denominator. Rather, they claim, the aim is to identify unnecessary deviation in the prevailing rules and to make them more compatible (BMW 2014: 27).

Although this sounds plausible and gives the impression of a simple and standardised procedure, regulatory cooperation is highly complex and politically extremely sensitive (Mildner/Ziegler 2008: 2). What, for example, is regarded as an unnecessary difference and thus as a trade barrier often cannot be defined objectively and depends not least on the underlying regulatory philosophy

in a particular economy or on citizens' values and expectations.

Thus in the EU the precautionary principle, mentioned in Article §191 of the Treaty of the Functioning of the European Union (TFEU), is applied in many economic sectors, such as food. In accordance with the notion 'better safe than sorry' the precautionary principle entails that temporary measures for the protection of consumers can be introduced if risks concerning a particular product or service cannot be ruled out with sufficient certainty. Products and services may thus be marketed only if extensive risk analyses have proved their safety and classified them as harmless to consumers. Conversely, it means that products and technologies can also be prohibited even if no scientific evidence of a risk is available. Critics of the precautionary principle thus argue that it can be used to disguise merely normative or protectionist restrictions under a scientific cloak, on the grounds of risk prevention.

The precautionary principle also exists in the United States, for example, in relation to medical products. However, many economic sectors are much more 'risk-tolerant'. Under the rubric 'generally recognized as safe' products are considered harmless until proven otherwise. If there is no scientific evidence of harm it is assumed that there is no risk to consumers. This approach is feasible in the United States primarily because consumers have, in the 'class action' system, an effective recourse to assert compensation claims against companies in the event of damage or loss.

This contrast between EU and US approaches to risk gives rise to the first dilemma in the negotiations on the transatlantic free trade zone: Europeans insist on sticking to the precautionary principle (BMW 2014: 12), while Americans – at least in many economic sectors – regard this as a thorn in their side (Maine Government 2013).

On the other hand, there are also economic sectors which in the United States are subject to very much stricter regulations and legal provisions, which could be interpreted in the EU as trade barriers. An example is the market for medical products or devices (on this see Section 3.2.2).

One possible way of circumventing this dilemma is the mutual recognition of standards

(see Section 2.2.2.2) or a corresponding equivalency agreement for particular sectors (see Section 2.2.2.3). Thus products could be introduced into the other economic area notwithstanding differing requirements and standards, to be marketed there without special labelling. However, if it is assumed that a higher level of protection entails higher production costs, such a regulation could easily lead to market distortions, with imported goods offered on more favourable terms than those produced domestically. As a result, at some point the national legislator is likely to feel compelled to adapt its originally stricter rules 'downwards' in order to escape the reproach of 'reverse discrimination' (VZBV 2014a: 26). This, in turn, would instigate a 'race to the bottom' in which existing protection standards are sooner or later – in the teeth of the original, quite different intentions – levelled down. Such instruments should thus be implemented only if the regulatory aims and outcomes are (almost) identical, however much the regulatory instruments differ.

Similarly, ethical differences may mean that certain products may not be marketed in the other economy; one example of this is food containing genetically modified organisms. Ethical considerations can be interpreted by the other side as unnecessary trade barriers, which would have to be removed in the course of creating a free trade zone by means of mutual recognition or equivalence.

The situation is even more complex if statutory requirements confront a system of voluntary self-regulation. Convergence of standards in this instance would entail either a drastic infringement of the regulatory structures of one negotiating partner or the total renunciation of the prevailing regulations of the other.

Once again, it becomes evident just how complex regulatory cooperation can be because it can curtail the sovereign rights of the negotiating parties and requires a high level of trust in the regulatory competences of the negotiating partner, especially when such sensitive areas as consumer protection, food safety and environmental protection are concerned (Mildner/Ziegler 2008: 2).

Table 1 summarises the key instruments for removing non-tariff trade barriers, potential dangers to their implementation from a consumer standpoint and minimum requirements for ensuring consumer welfare.

2.3 Fundamental Goals of Consumer Policy

What is special about the planned Transatlantic Trade and Investment Partnership is that – notwithstanding its possibly misleading title – it is not merely a trade agreement; rather the chief negotiators explicitly hold out the prospect of increasing consumer welfare (Federal Government of Germany 2013: 12).

Consumer welfare, however, should not be measured solely in monetary terms, but also in terms of whether basic consumer rights are preserved. These rights were authoritatively shaped by the consumer policy goals formulated by US President John F. Kennedy in 1962 and codified internationally in 1985 by the *UN Guidelines for Consumer Protection*, last updated in 1999. At issue here are the following seven fundamental goals of consumer policy (United Nations 2003):

- (I) **Safety:** The protection of consumers from hazards to their health and safety.
- (II) **Economic interests:** The promotion and protection of the economic interests of consumers.
- (III) **Information:** Access of consumers to adequate information to enable them to pursue their economic interests.
- (IV) **Consumer education:** Access to consumer education, including education on the environmental and social impact of consumer choice and consumers' economic interests.
- (V) **Compensation for damages:** Availability of effective consumer redress.
- (VI) **Freedom of association:** Freedom to form consumer and other relevant groups or organisations and the opportunity of such organisations to present their views in decision-making processes affecting them.
- (VII) **Sustainable consumption:** The promotion of sustainable consumption patterns.

Table 1:

Overview of regulatory instruments and their dangers from a consumer perspective, together with minimum requirements

	Regulatory dangers from a consumer perspective	Minimum requirements to ensure consumer welfare
Harmonisation	• Harmonisation to the 'lowest common denominator'	• Harmonisation at a high level – However, this requires comparatively similar levels of regulation and regulatory approaches.
Equivalence	• Market distortions and 'race to the bottom'	• This instrument should be applied only if the regulatory objectives and outcomes are (almost) identical, however much the regulatory instruments differ.
Mutual recognition	• Market distortions and 'race to the bottom'	• This instrument should be applied only if the regulatory objectives and outcomes are (almost) identical, however much the regulatory instruments differ.
Exchange of information	• One-sided focus on removing trade barriers – without taking into consideration consumer welfare	• Also taking into consideration issues of consumer welfare in a broad sense (on this see Section 2.3).

Source: Authors' table.

If one thus wishes to evaluate the effects of TTIP on consumer welfare there is no avoiding an analysis of the effects on these fundamental consumer rights. Of particular importance to the present analysis are the five aspects of safety, economic interests, information, consumer education and sustainable consumption (Figure 2). Such analyses can easily be subject to conflicting aims. For example, safety requirements might be set so high that the costs are disproportionate, to the detriment of consumers' economic interests. A balance has to be struck between such conflicting aims.

2.4 Evaluatory Framework

In order systematically to evaluate the public discussion of the Transatlantic Trade and Investment Partnership from a consumer standpoint we need an evaluatory framework. The basis for

such a framework is provided by the instruments for removing non-tariff trade barriers identified in Section 2.2.2.² Depending on which instrument is eventually chosen for the integration of the transatlantic market in the various sectors and economic areas, the implications for consumer welfare will differ. This can, in accordance with Section 2.3, be defined in terms of the five key goals of consumer policy. Thus, for example, more intensive exchange of information could primarily affect consumer interests in information and education, while decisions on equivalence or mutual recognition would rather affect economic interests and consumer safety. Figure 3 presents the evaluatory framework in graphic form. In Section 3 the instruments that are the focus of the public debate in the individual submarkets are highlighted. Likewise, the implications to be expected with regard to the goals of consumer policy are identified.

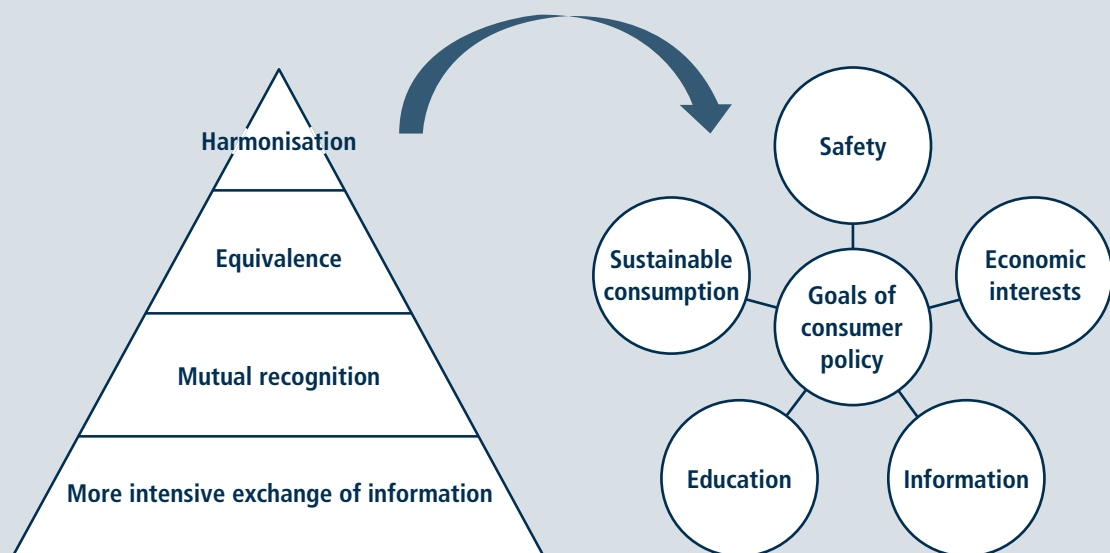
² The consumer-policy implications of the removal of tariff trade barriers are not the subject of this study and thus are not included in the evaluatory framework. On this see also the remarks in Section 1.3.

Figure 2:

Five fundamental goals of consumer policy

Source: Authors' graphic.

Figure 3:

Impact of instruments for removing non-tariff trade barriers on the goals of consumer policy

Source: Authors' graphic.

3. Analysis of Selected Submarkets

Based on the evaluatory framework presented above, in this section we analyse the potentials and risks of the free trade agreement between the EU and the United States for submarkets of particular relevance to consumer policy: food and nutrition, drugs and medical products, data flows and data protection, and financial services. The basis of the analysis is formed by the prevailing standards and the current state of the public debate, from which various cooperation scenarios are derived and, in conclusion, evaluated with regard to consumer welfare.

3.1 Food and Nutrition

In 2012, goods and services to the value of 456 billion euros were traded between the EU and the United States. Only 15 billion euros of this was accounted for by exports of agricultural products and foodstuffs from the EU to the United States and 8 billion euros by agricultural imports from the United States (DBV 2014: 2).

Despite this relatively low proportion, food and nutritional products, because of their direct and sometimes even emotional associations for consumers, at present represent the most sensitive and controversial area of the negotiations on TTIP, and time and again, because of the evidently incompatible agricultural and nutritional cultures, come to the fore in the public debate.

3.1.1 Prevailing Standards by Transatlantic Comparison

If one compares the regulatory systems of the EU and the United States in the area of food and nutrition it becomes apparent that the main points of difference arise because the two systems

are based on fundamentally different approaches to agriculture and nutrition in society (BÖLW 2014).

While the EU – among other things, in response to the BSE crisis – has consolidated its risk-averse nutrition and agricultural policy, in the United States the consensus remains that primarily the market can and should provide for a minimum level of food quality and safety. This difference in regulatory philosophies comes out most clearly from the disparate approaches to risk management: the EU regulates potential risks to consumers by applying the precautionary principle laid down in the Regulation on food and feed safety (Regulation (EC) 178/2002). This means that only those products are permitted for processing or direct sale that have been proved to be harmless to consumers. In the United States, by contrast, the view is that it is scientifically impossible to prove that something is totally safe (21 CFR 170.3(i)), for which reason products are permitted onto the market until it has been proven that they constitute a danger to consumers.

These different approaches to risk management are particularly evident with regard to the regulations on the introduction onto the market of genetically modified organisms (GMOs). In the EU the European Food Safety Authority (EFSA) is responsible for the risk assessment of GMOs for use in food or cultivation. On the basis of its assessment the European Commission and the member states decide whether GMOs are to be put on the market or not. These regulations apply regardless of whether the product to be accredited is entirely new or has already been permitted in another country. In the United States, by contrast, there is no official approval and testing procedure for putting GMOs on the market. Based on the assessment of the Food and Drug

Administration (FDA) that GMOs are in substance equivalent to conventional organisms (FDA 1992) the producing companies alone are responsible for the risk assessment of their products (BEUC 2014: 8).

These different authorisation requirements thus explain the differing dissemination of GMOs on the European and the US markets: while in the EU in 2012, a mere 0.12 per cent of arable land was cultivated with genetically modified plants (Friends of the Earth Europe 2013: 1), in the United States in comparison year 2013 the figure was already 50 per cent (Fernandez-Cornejo et al. 2014: 9).

Another decisive difference is that in the EU – in contrast to the United States – the labelling of foods with GMO content is legally mandatory (Regulation (EC) 1830/2003) and furthermore the traceability of GMOs and products derived from these organisms must be guaranteed through the whole production chain. These provisions are often regarded as unnecessary by the US side and interpreted as trade barriers because information of this kind could, in their view, send the wrong signal about the safety of the products concerned (Blenkinsop 2014). However, recent surveys show that US consumers also want labelling of this kind: as many as 93 per cent expressed a wish for explicit labelling of genetically modified foods (Kopicki 2013). This, among other things, explains why two US states (Connecticut and Maine) have already enshrined the labelling of GMOs in law (Wilson 2014).

It is also a key characteristic of the European system that, besides product risk assessment, 'other factors', such as ethical considerations, also explicitly influence legislation in the area of food and nutrition (TACD 2013b: 2). Thus the European Commission is currently in consultation on the approval of cloning technology for food production. Notwithstanding the EFSA's classification of this technology as harmless to human beings (EFSA 2012; VZBV 2014b: 3) the Commission is considering banning cloning and the marketing of foods derived from cloned animals (proposed directive COM 2013/892 and COM 2013/893). This would take on board the ethical concerns of the European population concerning this technology (European Commission 2008).

The situation is similar with regard to the hygiene standards applied to meat production in the EU. Although the handling of carcasses with chlorine compounds has been classified by both the EFSA (EFSA 2005) and the German Federal Institute for Risk Assessment (BfR) as harmless to human beings (BfR 2006), the EU has retained its ban on this method and the principle of comprehensive process hygiene in the slaughtering process. On this basis, every step in meat production – that is, 'from the field to the plate' – must take place in accordance with the strictest hygiene standards, so that the risk of zoonoses is minimised from the outset. In principle, EU law permits the surface cleaning of foods of animal origin with other substances apart from drinking water (Regulation (EC) 853/2004), but these measures are supposed to be applied only in a complementary way and not exclusively (BfR 2014: 1). In the United States, by contrast, there is no comprehensive hygiene concept for the purpose of curbing or avoiding the contamination of animals throughout the production chain. There the chemical decontamination of carcasses is always the last stage of production for the purpose of killing off illness-causing germs on the surface of meat and thus ensuring the safety of products.

Furthermore, guidelines differ in the EU and the United States concerning the use of antibiotics in animal husbandry. Thus in the EU the admixture of antibiotics to animal feed has been totally banned since the coming into force of the Regulation on animal feed additives (Regulation (EC) 1831/2003) on 1 January 2006 and their administration permitted only for veterinary purposes. As a further step to counteract the progressive spread of antibiotic resistance among consumers, in Germany an amendment to the Medicines Act came into force on 1 April 2014. The aim of this amendment is to restrict the use of antibiotics in the treatment of sick animals to an absolute minimum. In the United States, by contrast, the non-therapeutic use of antibiotics to boost growth continues to be permitted and is applied by the meat industry on a large scale (indeed, 80 per cent of all antibiotics sold in the United States are for the fattening of animals; Union of Concerned Scientists 2013).

Different standards are applied to the growth hormone Ractopamin, too, which in the United States was officially permitted in 1996 by the FDA (Animal Drug Availability Act) and since then has been used for 'more efficient' meat production, especially in the case of pigs. In the EU (as well as in 160 other countries) Ractopamin is banned (RL 96/22/EC).

On the other hand, there are areas in which the United States seeks to curb health risks to consumers that in the EU are tolerated. One example of this is the market for milk and milk products. In order to guard against food poisoning the sale of raw milk or raw milk products is banned in many US states and the FDA on its home page expressly warns against the consumption of these products (FDA 2012a). In the EU, by contrast, cheese varieties made from raw milk are classified as speciality items and can be sold freely. Milk certification systems in the EU and in the United States also differ, for example, concerning the permissible plate count and proportion of somatic cells or with regard to requirements concerning product traceability along the production chain (AMS 2011).

Another example of diverging regulatory systems involves the differing regulatory protection of geographical indications and designations of origin. While in the EU designations of origin are reserved for products 'that were produced, processed and prepared in a defined geographical area using recognised and proven know-how' and geographical indications protect products in relation to which there exists at least at 'one of the stages of production, processing or preparation a connection with the area' (Regulation (EC) 510/2006), in the United States such designations represent labels for identifying particular product groups. Accordingly, the name 'cheddar' is not reserved for cheeses produced in Cheddar (a village in the county of Somerset in the United Kingdom), but all types of cheese produced using the cheddar process (USPTO 2013).

3.1.2 Current State of the Public Debate

Although food and agricultural products, as already mentioned, make up only a relatively small proportion of total transatlantic trade volume, agreements reached by the negotiating partners in this area are extremely sensitive and threaten the success of TTIP. For example, US Agriculture Secretary Tom Vilsack has declared: 'There can't be a trade agreement without serious and significant commitment to agriculture' (Kanter 2014).

As shown in Section 3.1.1, the viewpoints and regulatory philosophies of the United States and the EU sometimes diverge so radically that doubts have been expressed by many about whether the systems can be reconciled at all and, if so, whether this would benefit consumers (Grain 2013; Lorenzen 2014).

Generally, the point is made that a transatlantic partnership offers an opportunity to lay down new global quality criteria for food and sustainable agriculture (Lorenzen 2014) and in this way to substantially increase food safety and consumer welfare (BEUC 2014: 3). However, this could succeed, according to civil society representatives, only if harmonisation is achieved at the highest level of consumer protection and, at the same time, national autonomy is retained with regard to regulation. All areas in which this does not happen should thus – it is demanded – be excluded from the negotiations (TACD 2013b: 1).

The German government and representatives of the European Commission also emphasise that the EU's right to take decisions in accordance with the precautionary principle and ethical considerations is not on the table within the framework of TTIP (BMW 2014: 12; European Commission 2013c). Conversely, however, this also means that no intervention with regard to the US regulatory philosophy will be possible in the course of TTIP. At the end of the day, the US government considers its regulatory philosophy with regard to food as more sensible and more consumer-friendly and never tires of emphasising that enhanced regulatory cooperation will be possible only if the precautionary principle and soft (in the sense of 'not scientific') factors are renounced in the future (American Meat Institute

2013; Blenkinsop 2014). On top of that, for both the United States and the EU it would not be politically feasible to abandon their respective regulatory philosophies.

Against this background it appears difficult if not impossible to broadly harmonise standards in the area of food and nutrition. At the same time, the worry is growing that package deals, in which one side makes concessions in one area in return for the other side making concessions in another, will result in infringements, regardless of the original intentions (Lorenzen 2014).

Furthermore, equivalence efforts or the mutual recognition of standards in the area of food and nutrition are extremely controversial because of the substantially diverging agricultural and food cultures (BEUC 2014: 5; VZBV 2014a: 4). By such means products would obtain access to the European market that do not comply with its requirements concerning risk assessment or ethics. If the demands of the US side were met in this regard it would not even be permitted to label such products, on the ground that that might hinder their marketing (Blenkinsop 2014). This would be of particular relevance in relation to products with a GMO component, about which consumers in Europe have strong reservations (Kanter 2014). However, the comprehensive labelling of foods in particular is one of the fundamental objectives of consumer policy (on this see Section 2.3) and is therefore an expression and key part of European information policy (Directive 2000/13/EC) aimed at enabling consumers to make informed purchasing decisions. This should not be sacrificed as a concession to supplier interests within the framework of TTIP (BEUC 2014: 2).

The producer side also argues that, besides protection of consumers in respect of the mutual recognition of standards, the protection of suppliers is also crucial (DBV 2014: 5). Thus, for example, meat can be produced up to 80 per cent more cheaply in the United States than in the EU, due, among other things, to less strict environmental regulations and different production standards (German Bundestag 2014b). If this meat – presumably without even being labelled as such, on the grounds that that would be ‘discriminatory’

and hinder marketing, as already mentioned – got onto the European market, European producers would inevitably be at a competitive disadvantage. In order to counteract such market distortion, sooner or later European producers would demand that EU standards be lowered to the level of the US side in order to restore competitiveness (VZBV 2014a: 34). The upshot would be that the mutual recognition of standards would indeed result in harmonisation of standards, but at a lower level.

Equally, it could be argued that the quality of the EU’s process-oriented and precautionary production approach might have the effect in the American market of eventually forcing US producers to raise their standards. However, due to the fact that consumers would not be able to distinguish between European and US products because the necessary labelling would be virtually impossible, such a scenario is rather unlikely.

This being the case, the greatest potential for transatlantic cooperation from a consumer standpoint, given the clash of production standards and regulatory philosophies, would appear to lie in more intensive dialogue and the aggregation of transatlantic forces and competences in the area of food and nutrition, boosting consumer welfare and safety on both sides of the Atlantic. Three fields of action in particular should be emphasised:

First, often mentioned in this context is the establishment of a common early warning system in the food sector, as well as improvements in the traceability of products throughout the transatlantic production chain (BEUC 2014: 9; TACD 2013b: 3; VZBV 2014a: 4). These measures are relevant primarily because if trade intensified in the wake of TTIP more food products would circulate in a much larger market. Accordingly, effective mechanisms must be put in place to cope with a possible food scandal, which would make it possible to identify the source of contamination rapidly and also to ensure effective hazard communication in the two consumer markets. The EU and the United States could rely on existing structures for this purpose – the RASFF system in the EU, the Food Safety and Inspection

Services in the United States and the WHO and FAO's INFOSAN network – combining them in a judicious manner to thereby not only improve consumer safety, but also set international standards.

Secondly, there is also the possibility of transatlantic cooperation in combating antibiotic resistance among consumers (BEUC 2014: 10; TACD 2013b: 4). According to the Center for Disease Control and Prevention, this led to 23,000 deaths in 2013 in the United States alone (Center for Disease Control and Prevention 2013: 6). Even though the FDA does not officially regulate the use of antibiotics in food production it recently at least published guidelines on reducing drug utilisation (FDA 2013). This could be the first step towards a rethink. As early as 2009, moreover, a transatlantic Taskforce on Antimicrobial Resistance (TATFAR) was set up to explore the potential for cooperation between the EU and the United States in combating the rise of antibiotic resistance across the globe. These structures could form the basis of an international pioneering role in the wake of the creation of a transatlantic trade partnership.

Thirdly, consumer organisations are cautioning that the global problem of (child) obesity can be addressed and minimised only with a united international effort. In the wake of TTIP, measures could be developed and promoted to improve consumer information, for example, with regard to the fat and caloric content of food or raising awareness among children (BEUC 2014: 11f.; TACD 2013b: 6).

3.1.3 Summary Evaluation

The public debate shows that closer cooperation between the EU and the United States in the area of food and nutrition can have an effect on the established consumer-policy goals in their entirety and thus exert great influence over consumer welfare in this area.

As has been made clear, the sharply diverging regulatory philosophies in the food and agricultural goods sectors hinder or even make less desirable the transatlantic harmonisation of

standards and regulatory systems because such an approach would impinge on the negotiating partners' regulatory competences too much.

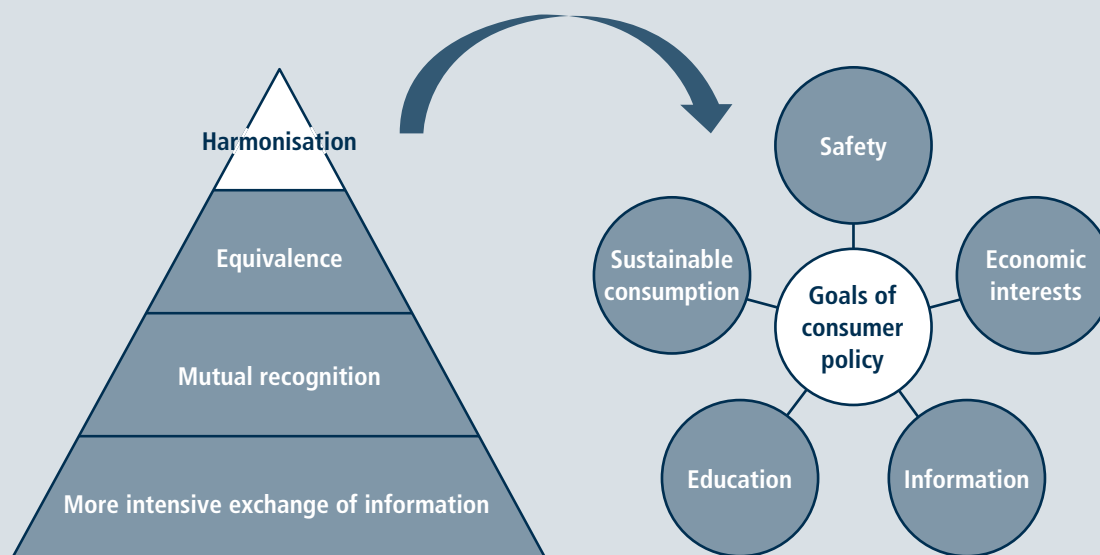
Although taking the removal of non-tariff trade barriers down a notch to equivalence or mutual recognition has been demanded in many quarters the effects would tend to be negative rather than positive: it is true that consumer prices would probably fall due to a more abundant supply and more favourable (to producers) conditions of production, but at the same time European requirements concerning product safety would cease to be met because in the United States other requirements are applied to the authorisation and production of food. Even comprehensive consumer information could no longer be entirely guaranteed because the lack of product labelling could make it impossible to tell where a product comes from and under what conditions it was produced. Even the sustainable consumption desired by so many consumers – which, for example, would preclude certain forms of animal husbandry practised in the United States – would not be feasible under such conditions, or only with great difficulty.

The situation is different in areas in which transatlantic cooperation would be strengthened primarily through an increase in communication and exchange of information. Thus the establishment of an international food early warning and traceability system could have a positive effect on general consumer safety and information, with no downside.

Similarly with regard to intensive cooperation in combating antibiotics resistance and obesity, this in particular would have a positive effect on all aspects of consumer policy and could even entail economic gains for consumers because health care systems would feel the long-term benefit of less ill health. This would also be the case if the use of antibiotics could be reduced, although consumer prices may rise due to changes in the conditions of production, so that the two would have to be balanced against one another.

Figure 4 summarises the assessment of the current state of the debate.

Figure 4:

Consumer-policy evaluation in the area of food and nutrition

	Safety	Economic interests	Information	Education	Sustainable consumption
Harmonisation of production, hygiene and safety standards	X	X	X	X	X
Mutual recognition/equivalence with regard to production, hygiene and safety standards	-	+	-		-
Introduction of transatlantic food early warning and traceability system	+		+		
Collaboration in combating antibiotics resistance	+	+/-			+
Collaboration in combating (child) obesity	+	+	+	+	+

Source: Authors' graphic.

3.2 Drugs and Medical Products

Enhanced regulatory cooperation between the EU and United States in the areas of drugs and medical products was one focus of the fourth TTIP negotiating round in March 2014 (European Commission 2014h). Because the two areas are regulated differently we shall discuss them separately in what follows.

3.2.1 Drugs

Drugs are substances or preparations of substances used either on or in the body for the treatment, alleviation or prevention of illnesses, suffering, physical injury or discomfort (§2 Arzneimittelgesetz [Drugs Act]). Almost all drugs require – in both the EU and the United States – an official drug approval in order to be put on the market.

Within the framework of the relevant approval procedure, testing determines whether the drug in question is effective and safe and has the requisite pharmaceutical quality (BfArM 2013c).

3.2.1.1 Current standards by transatlantic comparison

In the EU a distinction is made between centralised and decentralised procedures in relation to the approval of pharmaceutical products. Centralised approval procedures are necessary, in accordance with Regulation (EC) 726/2004, if a preparation is to be accredited and authorised throughout the EU or if it is a pharmaceutical product with new active ingredients for serious illnesses. In the case of this kind of procedure the European Commission issues the approval. The European Medicines Agency (EMA) is responsible for the organisational implementation of the procedure in cooperation with national authorities. Decentralised procedures are applied if a product has already been accredited in an EU member state and approval is being sought in one or several other states (*mutual recognition procedure*) or if the approval is requested simultaneously in several EU member states (*decentralised procedure*) (Paul-Ehrlich-Institut 2011).

In April 2014 the Council of Ministers proceeded further with EU harmonisation of the approval of pharmaceuticals by adopting the Regulation on Clinical Studies. According to the Regulation pharmaceutical producers will in future have to submit only one application to carry out studies in several EU member states. By the time the Regulation comes into force in 2016 an electronic submission portal is to be established at the EMA. This submission portal will be connected to a database in which summaries of the results of clinical studies submitted for approval will be publicly accessible (BMG 2014).

In the United States the Food and Drug Administration (FDA), in cooperation with the Center for Drug Evaluation and Research (CDER), is responsible for official approval of the production and national sale of pharmaceuticals. The approval process is initiated at a very early stage with an application by the producer for

permission to commence clinical studies (Investigational New Drug Application). The authorisation procedure has eight or nine steps. Only when all the necessary studies and information are in hand does the pharmaceutical company submit a final application for approval (a New Drug Application), which the FDA evaluates and makes a final decision on (FDA 2014).

Although the two regulatory systems use different assessment criteria with regard to approval (or rejection) of a pharmaceutical, since 1990, within the framework of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), there have been efforts to harmonise approval-relevant standards and pharmaceutical testing lines, as well as guidelines for Good Manufacturing Practice (GMP), between the United States, the EU and Japan. The ICH's aim is to adapt the criteria for studies to be carried out and other documents necessary for approval in such a way that unnecessary duplication is minimised for the producing companies in the approval process (ICH 2014). Nonetheless, it often happens that pharmaceuticals are recognised in one economic area, while approval is denied in another.

Generic medicines – copies with the same active ingredients as a reference preparation whose patent has expired (GBE 2014) – can be put on sale in the EU under simplified approval conditions. Although the producer has to prove the pharmaceutical quality of its product no additional preclinical and clinical studies have to be performed. Scientific proof that the generic medicine is comparable with the reference pharmaceutical is sufficient to obtain approval for sale. Generally a bioequivalence study has to be submitted that proves that the generic medicine brings about the same active ingredient concentration in the body as the reference preparation (BfArM 2013a; EMA 2012: 2). The same applies with regard to the approval of generic medicines on the US market by the FDA (Kefalas et al. 2011: 119).

For the past 15 years or so the European pharmaceutical sector has increasingly focused on so-called '*biosimilars*', copies of bio-pharmaceutical medicine whose patent has expired. From the

beginning the EU has striven to create a positive development climate for biosimilars – for example, by establishing a transparent approval framework at the EMA – and at present is a global pioneer in biosimilars (Dingermann/Zündorf 2013). For example, the guidelines on biosimilars published by the WHO in 2010 were modelled on the prevailing EU standards (VFA 2011). For the approval of biosimilars the EMA demands – in contrast to generic products – comprehensive proof of quality, effectiveness, safety and tolerability, more or less along the lines of an initial approval. This is due to the fact that biosimilars are only similar to the original preparation, but never identical. The United States is currently in the process of getting corresponding guidelines – ‘Guidance for Industry Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product’ – off the ground (VFA 2013: 2ff).

To date, no effort has been made to harmonise pricing and reimbursement in the European Union. In accordance with the subsidiarity principle the authority to set prices lies with individual member states (Art. 168, para 7 TFEU and Art. 5 TEU). In the face of ever increasing health care costs, however, many European governments have developed mechanisms to cut costs and have instituted reforms of the health care system to curb rising expenditure, while ensuring comprehensive health care provision. For example, in Germany, since the coming into force of the Act on Reorganisation of the Pharmaceutical Market (Arzneimittelmarktneuordnungsgesetzes – AM-NOG) on 1 January 2011, the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) negotiates the prices of innovative medicines, taking into account their specific use, directly with the pharmaceutical industry. Furthermore, since 2003 pharmaceutical companies in Germany have been statutorily obliged to grant health insurance funds a rebate on patent-protected medicines and, since the coming into force of the Economic Optimisation of Pharmaceutical Care Act (Arzneimittelversorgungs-Wirtschaftlichkeitsgesetzes – AVWG) in 2006, pharmaceutical companies have had to agree rebate

contracts for generic drugs (AOK-Bundesverband 2014).

On the decentralised and ostensibly competitively organised private health market in the United States, by contrast, the pricing of pharmaceuticals is not subject to any state control. Instead, prices are set in direct talks between producers and buyers (Rychlik 2010: 64). The purchase and distribution of medicines is undertaken in the US system by so-called ‘pharmaceutical benefit managers’, who negotiate the prices for private health insurers, but also for pharmacies. In this system producers have to offer substantial rebates in order to obtain contracts with the biggest possible sales volume. In order to remain economically viable, prices for consumers without insurance cover are correspondingly over the odds (Wasem et al. 2005: 62f).

Under the Community Code Relating to Medical Products for Human Use (Directive 2001/83/EC) the advertising of prescription drugs is prohibited in the EU. In the United States, by contrast, it is permitted to address consumers of pharmaceuticals directly via TV, radio or print ads.

3.2.1.2 The current state of the public debate

In May 2014 the European Commission published an official position paper on the pharmaceutical sector (European Commission 2014f). From this it is apparent that transatlantic co-operation with regard to pharmaceuticals will be characterised by the following measures, as far as the EU is concerned:

- mutual recognition of inspections of good production practice;
- exchange of reliable information;
- harmonisation of approval requirements for biosimilars;
- enhanced collaboration on the approval of generic drugs;
- revision of the ICH guidelines on medicinal products for paediatric use;
- terminological harmonisation;
- parallel scientific consultation in the product development phase.

With regard to inspections of good production practice the European Commission in its position paper suggests a comprehensive review of existing systems on both sides of the Atlantic in order to identify equivalences and commonalities and, on that basis, to work out options for mutual recognition. Such recognition of standards would help to reduce unnecessary duplicate testing in the EU, the United States or third countries and thus lead to considerable cost savings for pharmaceutical producers (European Commission 2014f: 2). In any case, due to the development of the ICH guidelines on GMP there is already an intensive exchange of information between the relevant authorities in the EU and the United States. Thus the proposal of mutual recognition as regards GMP is not opposed by the health insurance funds, despite the insistence that the nature and scope of inspections must maintain their current high level (GKV-Spitzenverband 2014a).

The exchange of reliable information should, according to the European Commission's position paper, take place primarily by means of intensified dialogue between the responsible EU institutions, on one hand, and the FDA, on the other. This should involve, besides the exchange of, for example, GMP reports, the sharing of data and information from approval applications (European Commission 2014f: 2). This proposal has been welcomed by, for example, Germany's National Association of Statutory Health Insurance Funds because a standing dialogue on safety aspects or serious events with regard to market access could considerably improve patient safety (GKV-Spitzenverband 2014a: 7).

Representatives of the pharmaceutical industry also favour closer exchange between the relevant institutions, for example, with regard to data on clinical studies. At the same time, in a leaked 'TTIP wish list', they declare that it is essential that this exchange take place behind closed doors in order to protect confidential information and commercial secrets (Commons Network 2014: 9). However, this demand runs counter to the EU's Regulation on Clinical Studies, issued only in May 2014, according to which summaries of all studies submitted as part of

applications for the approval of new pharmaceutical products are to be published on the EMA website. Civil society representatives worry that this Regulation – as it were as a concession to the industry and to foster TTIP's chances of success – could be diluted (Commons Network 2014: 9; GKV-Spitzenverband 2014a: 7). A possible consequence of this would be that important empirical data might never be made available to public scrutiny and a crucial source of information for practitioners and consumers would be lost. The fact that this worry is not unfounded is shown by proceedings launched by two US pharmaceutical groups against the EMA due to the new transparency efforts (BMJ 2013). This case gives cause for concern, in particular with regard to the chapter on investor-state dispute settlement (ISDS) that may be included in TTIP (on this see Section 2.1).

The harmonisation of approval requirements for biosimilars that the EU would like to achieve within the framework of TTIP would provide an opportunity not only to help shape this development – against the background of the regulatory framework that is currently emerging in the United States – but also to counteract the emergence of parallel or even divergent approval systems (European Commission 2014f: 2). This, in turn, could entail direct benefits for consumers on both sides of the Atlantic because convergence or joint development of approval requirements would lead to more rapid and more favourable availability of biosimilars on the market, which would moreover bring with it prompt and sustainable relief for health care systems (GKV-Spitzenverband 2014a: 8). International approaches to the approval of biosimilars could also be decisively influenced by transatlantic cooperation (European Commission 2014f: 2).

In its 'TTIP wish list' the pharmaceutical industry does not come out directly against harmonisation with regard to biosimilars, but it would like to strictly regulate the reimbursement options for these products. Specifically, only bio-equivalent medicines – generics – would be the object of price negotiations with the health insurance funds (Commons Network 2014: 8). As a result, the price of biosimilars would thus remain high, thereby sharply restricting their availability for

patients. It is crucial here that this demand clearly impinges on the regulatory competences of EU member states, which use *pricing and reimbursement mechanisms* to ensure the functionality of their health care systems and comprehensive health care coverage. Specifically, the worry in the EU is that free pharmaceutical pricing could be demanded by the United States as an expression of free market access and that any attempt at regulation by EU member states in the pharmaceutical market could be interpreted as erecting trade barriers (GKV-Spitzenverband 2014a: 8; Maier-Rigaud 2014: 6). This could, in turn, have negative consequences for consumers because the costs of health care provision could rise and quality of provision accordingly fall.

In light of the free trade agreement concluded between the EU and South Korea in 2011 such a danger seems very real. The EU identified the South Korean pricing and reimbursement provisions in the pharmaceutical sector as trade barriers and insisted on greater transparency with regard to pricing and reimbursement practices, as well as non-discriminatory treatment of foreign providers (European Commission 2011: 11).

With regard to generics, the EU is seeking closer cooperation on the approval systems for such products, but what this collaboration will really look like remains unclear. The European Commission's position paper, however, suggests that, in particular, mutual recognition of bioequivalence studies and reference preparations is the aim (European Commission 2014f: 2). This could accelerate the approval of generic products and thus make them more rapidly available and at lower cost, which would directly benefit the health care system and consumers.

The planned *revision of the ICH guidelines on medical products for paediatric use and terminological harmonisation* can also be viewed favourably from a consumer standpoint. The development of uniform testing lines to verify the safety and quality of child medicines and general recognition of approval documents would do away with unnecessary expenditure on duplicate work, which would make it possible to introduce medicines on the transatlantic market more quickly and at lower cost. Furthermore, by establishing a uniform

terminology transatlantic dialogue would be improved and the registration and traceability of individual preparations would be simplified. More intensive cooperation and parallel scientific consultation in the product development phase would benefit consumer safety. Enhanced dialogue between the FDA and the EMA would curb the development of complementary and incompatible approval requirements for new pharmaceuticals from the outset and also raise the quality of preparations through greater knowledge.

Furthermore, there is also a worry that the US pharmaceutical industry will interpret the ban on active advertising of products as a trade barrier that has to be removed in a free trade zone. On the other hand, European organisations are calling for continued regulation of direct patient advertising for pharmaceuticals despite a single market (AIM 2014).

3.2.1.3 Summary evaluation

Evaluation of the current state of the negotiations shows that efforts towards closer cooperation in the pharmaceutical sector are focused on economic interests, consumer safety and consumer concerns about transparency and information.

For example, *mutual recognition of GMP inspections* could make transatlantic duplicate testing unnecessary and thus bring about considerable cost savings for pharmaceutical producers. This would have a direct effect on the economic interests of consumers because these cost savings could be passed on to them in the form of lower end prices.

Furthermore, continuous exchange of information between the EMA and the FDA or parallel scientific consultation in the evaluation of new preparations could impact positively on patient safety because the relevant technical knowledge would be shared across the Atlantic. To the extent that this information would be publicly accessible, transparency could also be increased for consumers and thus consumer information improved.

Harmonisation with regard to the approval of biosimilars and enhanced cooperation with regard to the accreditation of generics could also be

reflected in reduced end prices as a result of faster and simpler approvals which could thus directly affect consumers' economic interests. These measures would also help to increase general consumer safety because, for example, biosimilars could be put on the US market more quickly.

Equally, the harmonisation of the ICH guidelines on medical products for paediatric use and cooperation on harmonising terminology would lead to more safety and a lowering of end user prices due to reduced coordination costs.

However, permitting direct advertising to patients in the EU by harmonising with US practice

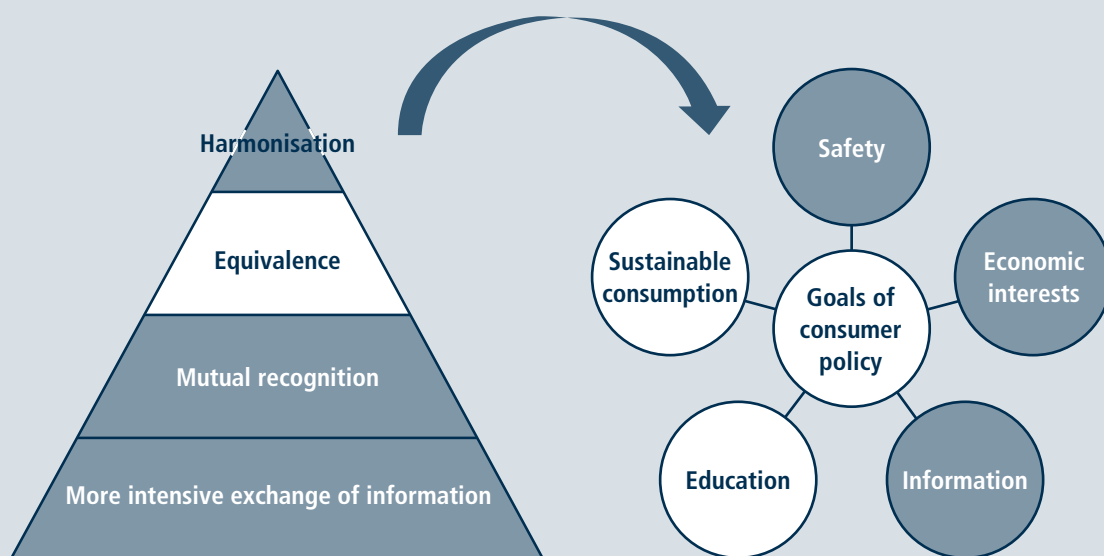
or mutual recognition could have a negative impact on safety, availability of information and their economic interests from the standpoint of European consumers.

The inclusion of regulations on pricing and reimbursement in TTIP would thus appear to be undesirable because this would involve a substantial infringement of the national rights of EU member states to provide their citizens with comprehensive health care.

The overall evaluation of the state of the discussion on the pharmaceutical sector can be summarised as follows (see Figure 5).

Figure 5:

Consumer-policy evaluation in the area of drugs



	Safety	Economic interests	Information	Education	Sustainable consumption
Mutual recognition of GMP inspections		+			
(Public) exchange of information and parallel scientific consultation	+		+		
Collaboration on approval of generics	+	+			
Further development of ICH guidelines	+	+			
Further development of harmonised terminology	+	+			
Harmonisation/mutual recognition of pharmaceutical advertising at the US level	-	-	-		
Harmonisation of pricing and reimbursement	X	X	X	X	X

Source: Authors' graphic.

3.2.2 Medical Products

The term ‘medical products’ covers a multitude of apparatus, instruments and other items used for medical treatment either in the body (for example, artificial joints or pacemakers) or on the body (for example, plasters or blood pressure-measuring equipment). Medical products differ from medicines in that they produce their effects without intervening in the patient’s metabolism (BfArM 2013b). Medical products are classified in different risk categories depending on their mode and duration of action. The European system distinguishes four, the US system three risk categories.

3.2.2.1 Prevailing standards by transatlantic comparison

In the EU the approval of medical products is regulated by Directives 90/385/EEC, 93/42/EEC and 98/79/EC and operates by means of the ‘system of notified bodies’. The notification of these independent bodies, which are entrusted with testing the conformity of medical products, is done by the individual nation-states. The notified bodies – such as DEKRA or TÜV – issue, in the case of a product’s certified conformity, the CE mark, which confers an entitlement to sell the product on the European market and in 30 associated countries. Producers may freely choose the notified body that will carry out the conformity test. Critics claim that this approach, in contrast to a system with a central approval body, harbours the risk that economic interests may influence the assessment of conformity. This may be detrimental to product safety (Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen [Advisory Council on the Assessment of Developments in the Health Care System] 2014: 50).

The purpose of the conformity evaluation procedure is to prove a product’s compliance with the prevailing requirements. In other words, the producer must demonstrate that its product meets all the requirements concerning quality, safety and harmlessness. A range of procedures may be selected for this purpose. Which conformity evaluation procedure is used for a product and the

extent to which the relevant notified body is involved in the procedure ultimately depends on its risk category. Thus with regard to most medical products in risk category I the producer itself declares and documents the conformity of its products without the specific involvement of the notified body (BfArM 2013b).

Also crucial is the clinical evaluation of medical products; that is, proof of the extent to which a product does what it is supposed to do and the ratio of benefits to undesired side-effects. In this instance the European system offers producers the option of referring to clinical studies of equivalent products, without having to gather its own data. However, minimum requirements for assessing the equivalence of products are lacking. Furthermore, at no stage of the testing procedure do the need for, effectiveness of and patient benefit from a medical product have to be proved explicitly (Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen [Advisory Council on the Assessment of Developments in the Health Care System] 2014: 51).

If the product is being put on the market for the first time the producer is obliged to gather information on its risks in use and, in the event of occurrences that led or could lead, directly or indirectly, to death or to a serious deterioration in the patient’s state of health (§2 Medical Products Safety Scheme Regulation), to notify the relevant federal authorities (BfArM 2013b). However, there is no duty of disclosure in the event of suspected cases of side-effects, in contrast to pharmaceuticals, for example (Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen 2014: 53).

Submission of data on medical products to the European database EUDAMED has been obligatory since 1 May 2011. However, EUDAMED is not publicly accessible (European Commission 2012b: 11). In addition, Germany’s Federal Institute for Drugs and Medical Products (Bundesinstitut für Arzneimittel und Medizinprodukte) publishes scientific studies of risk reports submitted and analyses the causes and effects of product defects, as well as any corrective measures that have been implemented.

The US system differs fundamentally from the European one. In the United States there is a central organ for the accreditation of medical products in the form of the FDA and the associated Center for Devices and Radiological Health (CDRH). This enhances the system's transparency and also prevents economic interests and product safety from coming into conflict.

Furthermore, as regards the approval of medical products the United States applies the precautionary principle. Thus products in the highest risk category, within the framework of a premarket approval procedure, obtain approval for sale on the US market only if their safety and effectiveness are adequately empirically confirmed and the FDA is provided with a variety of information and data pertaining to the assessment of its conformity. Producers of products in lower risk categories have to prove, within the framework of a premarket notification procedure, that their product is at least as effective and safe as a comparable product that has already been approved. This procedure ensures from the outset that only products that are not harmful to consumers get onto the market (Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen 2014: 54f).

Another advantage of the US system is that all studies carried out for the purpose of obtaining market approval are freely accessible in a database maintained by the FDA. Also available

are all decisions taken by the FDA on premarket approval, including the reasons and a comprehensive list of reported problems or recalls of medical products (Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen 2014: 55). This underlines the transparency and consumer-friendliness of the US system.

3.2.2.2 Current state of the public debate

The differences between the EU and US regulatory systems are summarised in table form in a 2012 report by the FDA (see Table 2), which also points out what, in its view, are the striking defects of the European system. It particularly criticises the inadequate and untransparent provisions on product approval, which have already harmed the safety and health of patients in many instances (FDA 2012b: 3f).

Against the background of the existing discrepancies it is not surprising that various stakeholders have called for harmonisation of European legal provisions with the US system (AIM 2014: 16; GKV-Spitzenverband 2014b: 2) and advocate that the issue be taken up in TTIP. Specifically, it has been asserted that mutual recognition would not be enough because this would not solve the problem of inadequate approval requirements for medical products in the EU (GKV-Spitzenverband 2014a: 4).

Table 2:

Comparison of the regulation of medical products in the EU and the United States

	United States	EU
Approval criteria	• Safety • Effectiveness (proof of real patient benefit)	• Safety • Technical performance (no proof needed of patient benefit)
Empirical evidence	• Valid clinical tests	• Limited data requirements (laboratory testing, summary of the scientific literature or small clinical studies are permitted)
Accreditation body	• Central approval body: FDA	• 'Notified' bodies (private organisations chosen and commissioned by the producer)
Transparency of the system	• Results of approval decisions (including the reasons for them) are publicly accessible	• Neither results of approval decisions nor the basis of assessment are publicly accessible
Reporting system	• Reporting on side-effects and product recalls to the FDA • Publication of information on the FDA's website	• Information on reported side-effects and product recalls are not publicly accessible

Source: Authors' table.

Up to now, the negotiators have striven to retain the different approval systems. For example, the idea is that transatlantic cooperation with regard to medical products should take the form of intensive exchange of information between the notified bodies and the FDA, along with the introduction of a joint product identification system for the traceability of risky products (GKV-Spitzenverband 2014a: 4f).

The latter has also been welcomed by civil society representatives as a sustainable means of improving patient safety. There have also been demands for bringing the requirements on transparent presentation of data on high-risk products up to the US level and – in accordance with US standards – making them publicly accessible (GKV-Spitzenverband 2014a).

3.2.2.3 Summary evaluation

Evaluation of the current state of the public debate on TTIP as regards medical products shows that the removal of non-tariff trade barriers impacts in particular on consumer safety, but also to a certain extent on economic interests and consumer information.

If one proceeds from mutual recognition of transatlantic approval standards – which to date

has been the official aim – the free trade zone could lead overall to a reduction in patient safety because protection standards on the European side could remain at the current poor level and the high US standards, on the grounds of market distortion, could sooner or later be adapted downwards (on this logic see also Section 2.2.2.5).

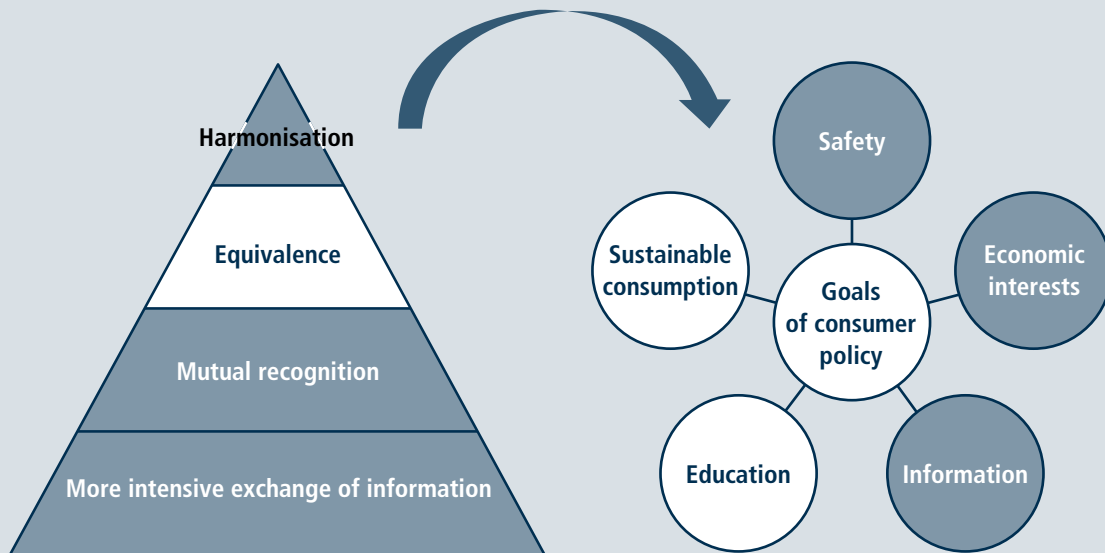
On the other hand, harmonisation of standards to the US level would impact positively on consumer safety in the EU because product approval requirements in the United States are stricter and transparency much greater.

Both measures would mean that producers would be spared unnecessary duplicate testing, which, one might assume, would result in falling prices and a positive effect on consumers' economic interests in both instances.

In addition, more intensive *exchange of information* with regard to test reports and decisions on approval applications, *the introduction of a joint product identification system* and the harmonisation of *transparency provisions* up to the US level could bring about a further increase in consumer safety. The latter would also benefit consumer information.

The results of this assessment are summarised in Figure 6.

Figure 6:

Consumer-policy evaluation in the area of medical products

	Safety	Economic interests	Information	Education	Sustainable consumption
Mutual recognition: approval	-	+			
Harmonisation of approval up to the US level	+	+			
Exchange of information about testing reports and approvals	+				
Introduction of a joint product identification system	+				
Harmonisation of transparency up to the US level	+		+		

Source: Authors' graphic.

3.3 Data Flows and Data Protection

According to the negotiators only aspects of data flows, but specifically not aspects of protection or data security, are part of the EU negotiating mandate and thus an object of the negotiations on TTIP (German Bundestag 2014a: 1). However, it is questionable whether intensifying the transfer purely of corporate B2B data, while at the same time excluding a corresponding exchange of personal information, is at all possible or even desired by all sides (VZBV 2014a: 50). Against this background data protection law issues are undoubtedly relevant, especially because levels of

data protection in the EU and in the United States can differ substantially from one another.

3.3.1 Prevailing Standards by Transatlantic Comparison

In the EU, personal data protection is laid down in the EU Charter of Fundamental Rights and in many member states also has constitutional status. Since 1995, furthermore, the Data Protection Directive (95/46/EC) has been in force in the EU, which provides EU member states with a framework for implementing data protection in national law.

However, implementation within the member states is not uniform. As a consequence, the level of data protection in Europe is fragmented and inconsistent at present, which falls short of the needs of a common internal market in the digital age (BMI 2014).

Against this background, in 2012 the EU initiated far-reaching reforms of the European data protection framework and presented a draft Regulation on general data protection law. This so-called Basic Regulation on Data Protection is supposed to bring about harmonisation of the legal framework in the EU as a whole and to replace the existing Data Protection Directive as soon as possible. The Basic Regulation on Data Protection regulates, among other things, how personal information is processed by companies with regard to online shopping, emails and in social networks. This concerns, for example, the so-called 'right to be forgotten' and the 'right to data portability' from one provider to another (European Commission 2012a). It is crucial that the regulations will apply, with the coming into force of the Regulation, to all companies that trade with European consumers, regardless of whether they operate from Europe or beyond (the so-called 'market location principle') (TACD 2013a: 2).

Data protection provisions are also currently undergoing a kind of reform process in the United States, although much less specifically and not comprehensively at a legally formalised level. For example, in 2012 the Obama administration published the document 'Consumer Privacy Bill of Rights', a list of guidelines concerning how data protection should look in today's information society and what consumers should expect from companies with regard to the trustworthy processing of their personal data (The White House 2012). Specifically, the document calls on companies and various interest groups, such as data and consumer protection agencies, to participate in working out enforceable codes of conduct, which the Federal Trade Commission (FTC) could then roll out in consumer law at the national level (Weichert 2012).

Although this proposal is indeed commendable, on the other hand it highlights the fact that hitherto data protection issues have been largely unregulated in the United States or if at all on a sectoral basis (Schmidt-Kessel 2014: 149). For example, at present binding data protection regulations exist only for health care providers, schools, film distributors and financial institutions. In all other consumer-relevant areas, however, the extensive storage and commercial use of personal data is entirely unregulated (TACD 2013a: 2) and data protection requirements are based, if they even exist, on self-regulation (Knoll et al. 2013: 32).

Against this background it is not surprising that the EU regards the US data protection framework as inadequate. In order to be able to support exchange of data with one of Europe's most important trade partners and also to address the important differences in the level of data protection between the EU and the United States, in July 2000 the Safe Harbor Agreement came into force. According to this agreement it is assumed that US companies have an adequate level of data protection if they publicly and unequivocally declare to the FTC that they are willing to comply with different principles with regard to personal data. Despite the fact that this is a voluntary pledge on the part of companies they do commit themselves to adhere to the principles of data protection and can be correspondingly sanctioned in the event of a violation (BFDI 2014).

More than 10 years since the agreement came into force, however, problems have only multiplied with companies' voluntary implementation of the data protection provisions, not to mention the implementation options made available by the relevant US authorities (TACD 2013a: 3). At the same time, the European Parliament has called for the suspension of the agreement due to the insurmountable breaches of trust revealed in the NSA spying scandal. The European Commission, however, continues to insist that Safe Harbor should be maintained, even though the data protection law guarantees would have to be urgently extended and developed (German Bundestag 2014a: 2; Krempel 2014).

3.3.2 Current State of the Public Debate

The free flow of information on the internet is as much an expression of freedom of opinion and of choice for consumers as it is a motor of economic development and company innovation. Against this background the negotiating partners agree that in the course of TTIP existing barriers to free data flow should be removed and no new ones should be created (TACD 2013a: 1; TBC 2013: 21f). At the same time, consumer representatives stress that the free flow of information is not the same as the free flow of personal data, to which special protection applies (Knoll et al. 2013: 31; TACD 2013a: 1).

From the standpoint of US corporations, however, this very standard of protection represents a significant trade barrier and a cause of major uncertainties and increased costs (Ermert 2013; Fontanella-Khan 2013). Specifically, they are calling for data protection standards to be dealt with in such a way that a 'non-discriminatory' balance is struck between individual data protection rights, on one hand, and minimal trade barriers, on the other (TBC 2013: 21). In order to achieve this, US standards need to be classified as adequate (Raul 2013: 15), the 'interoperability' of the system established or fostered (Raul 2013: 16; TBC 2013: 21f) and the necessary balance struck between levels of protection by means of self-regulation mechanisms, such as the Safe Harbor agreement (BITKOM 2013: 8; SIIA 2013: 4).

On the other hand, consumer and data protection agencies point out that US corporations have failed repeatedly to comply with minimum standards under data protection law, notwithstanding their public commitments (BFDI 2014). Furthermore, the mutual recognition of standards in the area of data protection clearly leads to distortions of competition at the expense of European companies (Fontanella-Khan 2013; VZBV 2014a: 51).

By contrast, there is consensus that TTIP, as a trade agreement, is not the right place to try to establish new transatlantic data protection

regulations from the ground up (Eurochambres 2013: 6; Knoll et al. 2013: 31; SIIA 2013: 3f.; VZBV 2014a: 51). However, it is occasionally emphasised on the US side that the current 'upheaval' in the two data protection systems should be taken as an opportunity to codify regulatory cooperation on data protection issues within TTIP (Raul 2013: 4). The contrary view, however, is that this is merely a pretext for preventing or at least diluting further tightening up of EU data protection law (Fontanella-Khan 2013).

What is not in question, however, is that in future the United States and the EU, regardless of TTIP, will have to cooperate more closely on data protection issues in order to adequately address the challenges of digital development, which recognise no territorial borders (TACD 2013a: 1). Specifically, this would involve, for example, more intensive cooperation between EU and US regulatory and data protection authorities, as well as transatlantic exchange of information on illegal data protection practices (VZBV 2014a: 51).

However, such enhanced cooperation on data protection issues is conditional on the successful conclusion of the European negotiations on the Basic Regulation on Data Protection (CDD 2013: 2; Eurochambres 2013: 1; VZBV 2014a: 51), so that any kind of influence from the US side on European data protection regulations is excluded (SPD-Bundestagsfraktion [parliamentary group] AG Digitale Agenda 2014: 1). Furthermore, it is crucial, within the framework of TTIP, to make sure that in the future national data protection provisions cannot be interpreted as trade barriers, against which action could be taken in the course of the free trade initiative or other instances of transatlantic cooperation (Schaar 2014).

Freedom of choice concerning where data are stored represents an expression of free data flows for many stakeholders (SIIA 2013: 2f.; TBC 2013: 20). On the other hand, there are considerations on strengthening European routing or the obligation to store and process sensitive data only in Europe (SPD-Bundestagsfraktion [parliamentary group] AG Digitale Agenda 2014: 2). Even if this would serve data protection and

general cyber-security it has been questioned in many quarters whether individual national solutions make sense (BITKOM 2013: 2; Clauß 2014), with warnings of a 'balkanisation' of the internet. Although this would boost security, it would at the same time diminish openness and consumer-friendliness (Fliegeauf 2013). Against this background, especially with regard to cyber-security, there are calls for closer transatlantic cooperation, which could also have an international impact (BITKOM 2013: 2). The success of such initiatives is indicated by the Global Alliance against Child Abuse on the Internet, brought into being by the European Union and the US Department of Justice, with which another 50 states are now associated.

3.3.3 Summary Evaluation

The discussion on data flows and data protection shows that efforts towards transatlantic cooperation in this area could exercise considerable influence on the consumer-policy dimension of security and information.

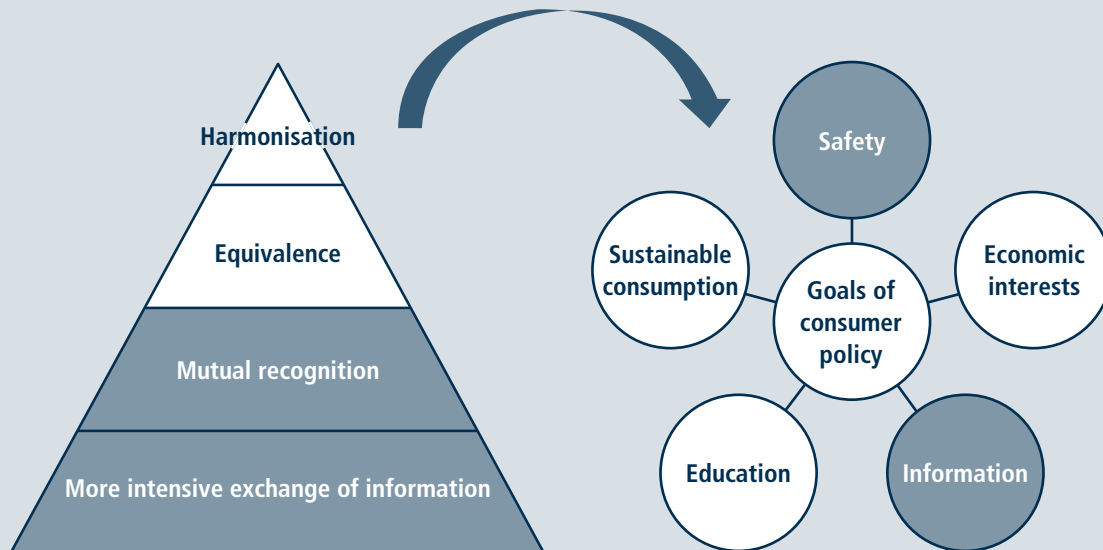
The previous section shows that data protection standards in the United States and the EU differ sharply and rest on totally different basic assumptions (data protection by self-regulation versus data protection as a fundamental right). Against this background harmonisation of standards appears difficult, if not impossible. This

assessment is supported by the fact that the legal regulations on data protection in the EU are currently in the process of reform, which will have to be concluded before harmonisation can even be considered.

If one assumes that the desired free data flows will not be possible without simultaneous transfer of personal data the demands of the US side for mutual recognition of data protection standards, complemented by self-regulation mechanisms, would have a negative effect on consumer welfare in the EU. In the United States binding and enforceable data protection regulations are still lacking, which means that US providers could continue to store and process data on a grand scale. This would affect not only the individual security of European consumers but also their right to information because it would remain unclear who is storing and processing their data and for what purposes.

On the other hand, enhanced cooperation as regards cyber-security, as well as ongoing transatlantic dialogue on data protection standards and violations, would have a positive effect on consumer security and information. These measures recognise that data traffic does not stop at national borders and that the dangers facing consumers in the digital world can best be addressed on a global basis. Figure 7 summarises the key findings of this section.

Figure 7:

Consumer-policy evaluation in the area of data flows and data protection

	Safety	Economic interests	Information	Education	Sustainable consumption
Harmonisation of data protection standards	X	X	X	X	X
Mutual recognition of data protection standards + self-regulation	-		-		
Exchange of information on data protection standards and violations	+		+		
Cooperation on cyber-security	+		+		

Source: Authors' graphic.

3.4 Financial Services

Easier market access for services is a key aim of the transatlantic free trade zone. Nevertheless the inclusion of financial services is a controversial issue in the TTIP negotiations that has not yet been resolved. While the United States, against the background of existing global coordination forums, doubts whether enhanced bilateral co-operation makes sense in this area (Donnan 2014), the European side holds that it is needed to combat the dangers of future financial crises effectively (European Commission 2014c).

3.4.1 Prevailing Standards by Transatlantic Comparison

The effects of the financial market crisis of 2007-2009 and the ensuing sovereign debt crisis on consumers on both sides of the Atlantic are still with us: vast sums of taxpayers' money were spent in both economies to bail out the financial system, while the continuing recession has led to higher unemployment and considerable income and wealth losses.

One of the main causes of all this was a very vulnerable financial system with international

intermediation chains of claims and obligations that substantially evaded regulation and oversight in key areas as the financial markets became ever more international, while supervision remained national (European Commission 2014e: 3).

In order to restore basic trust in the financial system and to ensure adequate protection against the consequences of systemic risks, far-reaching reforms of the financial sector have been launched or completed on both sides of the Atlantic over the past six years.

In the EU particular efforts have been directed towards stronger integration of the European financial system. Before this reform of the financial market the EU served only as a coordination hub for national financial supervision authorities and its competence was limited to enabling free movement of capital between the member states (Lehmann 2011: 3). Financial services provisions primarily had the purpose of minimal harmonisation which – in the case of cross-border market actors – often led to uncertainties and favoured regulatory arbitrage (European Commission 2014e: 3).

In order to comply with the declared requirement of more stability and efficiency in the European financial market, the EU is currently working on a comprehensive financial market reform, based as far as possible on G20 resolutions. An important part of this is the publication of a comprehensive set of regulations that is intended to facilitate consistent enforcement by means of common regulatory standards throughout the single market (European Commission 2014a). To date, around 40 legislative proposals have been developed in this context – for example, in relation to bankers' bonuses or deposit guarantee systems – and the legislative process launched (European Commission 2014d).

In order, moreover, to comply with the objective that 'no financial product, no financial market and no territory is to be able to evade adequate regulation and effective supervision' in 2011 the EU created the European System of Financial Supervisors (ESFS) with the European Banking Authority (EBA), the European Securities and Markets Authority (ESMA) and the European Insurance and Occupational Pensions Authority

(EIOPA). To complement this, the European Systemic Risk Board (ESBR) was set up to monitor the stability of the financial markets and to issue risk warnings in the event of systemic threats (European Commission 2014a; 2014e).

With regard to consumers, the newly created authorities should lead to a reduction in information asymmetries while, at the same time, increasing the transparency of the financial system and thus enhancing general trust in the financial sector. This includes, for example, measures on the marketing of mortgages, binding standards on financial consultation and the protection of small investors (European Commission 2014e: 8).

While reform of the financial market system in the EU has proceeded step by step, in the United States what has been presented as comprehensive reform of financial market structures has taken place with the adoption of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) in July 2010. Like the EU the United States would like to ensure more stability in the financial markets and has largely taken its bearings, again like its European counterpart, from the principles formulated by the G20 (Anderson 2010: 73f.). Specifically, the Dodd-Frank Act has three aims: (I) reform of the institutional supervisory and regulatory framework; (II) regulation of banks and financial institutions; and (III) regulations on investor and consumer protection (Kern 2010: 5).

The United States has purportedly thus made consumer protection a core element of its financial market reforms and has further underlined this by establishing an authority with specific responsibility for consumer protection in the financial sector within the Federal Reserve Bank, the Bureau of Consumer Financial Protection (BCFP). The task of the BCFP is to ensure that all laws on consumer protection in the financial sector are implemented; that consumers have unrestricted access to the financial market; and that finance is fair and transparent for consumers (Maier 2011: 21). New consumer protection regulations, which now fall within the remit of the BCFP, concern, for example, the mortgage market, in which creditors have to check new borrowers' ability to pay more thoroughly than previously; a

ban on certain incentives for expensive loans that are not consumer friendly; and raising the limit of the deposit insurance funds for private investors to 250,000 US dollars (Kern 2010: 8).

3.4.2 Current State of the Public Debate

The public discussion to date on a possible financial services chapter in TTIP can be characterised as very abstract. The available documents suggest that both the chief negotiators and the relevant stakeholders are primarily discussing whether regulations on financial services should be included in the free trade agreement at all. Only occasionally is reference made to possible specific effects on different stakeholders, such as consumers.

Overall, two opposing camps can be identified with regard to the question of whether including financial services makes sense. On one hand, there are the advocates of a TTIP financial services chapter. They are represented by the European Commission and US and European financial industry organisations. These actors see a danger that the regulatory efforts of both the EU and the United States in response to the financial market crisis – although based on the basic G20 resolutions – will lead to contradictory and fragmented regulatory systems, endangering global financial market stability and constituting substantial trade barriers in transatlantic trade (European Commission 2014b: 1f). The European side in particular criticises the fact that the Dodd-Frank Act is, in places, contradictory and discriminates against non-US financial institutions operating in the United States (Banking Association 2012: 2; 2014: 13; Kanter 2013; Losse/Handschuh 2014). Because, in their opinion, uniform transatlantic financial market regulations are not feasible due to divergent market structures and legal cultures, for example, the Banking Association, the European Commission and the TABC are calling for the EU and the United States to place more trust in one another's regulatory competences and are floating the idea of mutual recognition or equivalence of standards (Banking Association 2012: 2; European Commission 2014b: 3f.; TABC 2013: 3). In this way, they argue,

the prevailing regulatory philosophies and legal traditions in the EU and the United States could be preserved alongside transatlantic cooperation and the current reform processes in the two economies would not be hampered unnecessarily. Regulatory authorities would thus still be able to initiate and implement national guidelines, although always with an eye towards transatlantic cooperation and the effects on trade (European Commission 2014b: 4). In order to formalise this approach, a regulatory framework would have to be created within TTIP to enable the continuous and structured exchange of information, as well as regular assessments of new and existing financial market regulations with regard to their consequences for transatlantic trade, thereby boosting the efficiency and effectiveness of regulatory cooperation (Banking Association 2012; European Commission 2014b: 3; SIFMA and AFME 2014: 4).

In principle, the other side – namely, representatives of civil society and the US negotiators – welcome continuous dialogue between the United States and the EU concerning national implementation of international standards on reinforcing financial market stability (Johnson/Schott 2013: 2; TACD 2013c: 2; VZBV 2014a: 56). However, fundamental doubt has been cast on whether this should be within the framework of TTIP because the aim of creating a free trade zone with as few trade barriers as possible and the desire on both sides for a stable and consumer-friendly financial sector are not necessarily compatible (AFR 2013: 2; TACD 2013c: 2; VZBV 2014a: 55). On the US side the big worry is that existing and hard-won regulations designed to stabilise the financial sector and to protect consumers could be diluted because they avowedly represent a trade barrier to the European economy (Knoll et al. 2013: 28; Public Citizens 2013: 1; TACD 2013c: 2). Similarly, the purpose and usefulness of yet another – bilateral to boot – forum in a global financial market and against the background of existing international bodies, such as the Basel Committee on Banking Supervision, the International Organization of Securities Commissions and the G20 Rounds have been called into question, particularly by the US negotiators (AFR 2013: 1f.;

Donnan 2014; Finance Watch 2014: 2; Johnson/Schott 2013: 2; VZBV 2014a: 55). Although regular consultations are important for maximum transparency, nevertheless the negotiating partners must continue to be able to adopt stricter national regulatory measures, albeit based on international regulations. This is also, and above all, necessary because the United States and the EU are at different stages in their implementation of financial market reforms and are operating within different market and legal frameworks (Johnson/Schott 2013: 2ff.; TACD 2013c: 2).

3.4.3 Summary Evaluation

Our assessment of the state of the public debate on financial services shows that the removal of non-tariff trade barriers would have a particular effect on consumer safety, economic interests and consumer information.

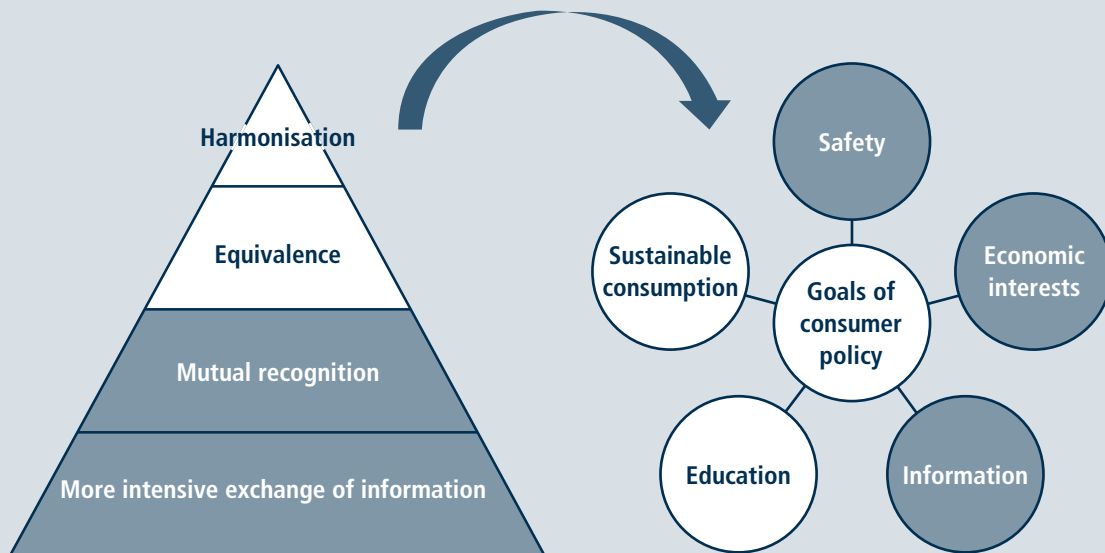
Given the existing differences in financial market structures and the general legal framework, transatlantic harmonisation of financial market standards would be difficult, if not impossible and, against this background, is not being considered by either the negotiators or the relevant stakeholders.

Both economic areas, in response to the financial market crisis, have initiated far-reaching reforms of the financial sector and are currently engaged in implementing them, albeit at different tempos. If mutual recognition of standards

were applied at this point, it could have a negative effect on the information situation of consumers because they would be in the dark concerning which regulations now apply to different financial products. This would, in turn, have direct consequences for their general safety. However, it could be that because financial institutions would no longer have to comply with two sets of standards, but only one, end prices for consumers would fall.

Continuous and structured dialogue between the United States and the EU on the transposition of international financial market standards in national legislation, by contrast, would give consumer safety and information a decisive boost because, on one hand, there would be more transparency with regard to the applicable rules and thus more informed and more robust decision-making would be possible. On the other hand, intensive transatlantic exchange of information could help ensure that contradictory financial market regulations are not enacted, which could result in lower end prices for consumers. However, more intensive dialogue is no guarantee of the equivalence of future financial services standards, so that this assessment has to be put in perspective. Notwithstanding the possible positive implications it is questionable whether, given the large number of existing global bodies, a financial services chapter in TTIP would make sense. The results of this assessment are summarised in Figure 8.

Figure 8:

Consumer-policy evaluation in the area of financial services

	Safety	Economic interests	Information	Education	Sustainable consumption
Harmonisation of standards in financial services	X	X	X	X	X
Mutual recognition of financial services standards	-	+	-		
Exchange of information on the implementation of global financial services standards	+		+		

Source: Authors' graphic.

4. Summary and Conclusions

What is distinctive about the planned Transatlantic Trade and Investment Partnership (TTIP) is that – as already mentioned (see Section 2) – it is not a trade agreement in the traditional sense, the idea of which is to boost the volume of (in this instance transatlantic) trade by removing customs duties. Instead, TTIP is focused primarily on the long-term removal of non-tariff trade barriers through enhanced regulatory cooperation. The instruments to be marshalled for this purpose range from intensive exchange of information between the negotiating partners, through the mutual recognition of product and production standards, to full harmonisation of regulatory principles (Section 2.2.2). Depending on which instrument is ultimately chosen for integrating the transatlantic market, different implications emerge for the welfare of individual consumers.

Consumer welfare is defined within the framework of the present study in terms of the fundamental goals of consumer policy, with a particular focus on safety, economic interests, information, consumer education and sustainable consumption (Section 2.3). Based on this, in Section 2.4 we introduced an evaluatory framework, with reference to the individual instruments for removing non-tariff trade barriers, by means of which in Section 3 we analysed the public discussion on TTIP in four submarkets – food and nutrition, drugs and medical products, data flows and data protection, and financial services – which are of particular importance to consumers.

We summarise the results of our analysis of the four submarkets in six theses. It is important to note, however, that this study does not claim to be exhaustive (see also Section 1.3), but is based on the analysis of the four submarkets.

Thesis 1: Transatlantic relations are characterised in a number of instances by fundamentally different regulatory philosophies, which preclude overall harmonisation or mutual recognition.

Analysis of the four submarkets shows that the EU and the United States in some instances have fundamentally different regulatory philosophies and traditions, which not only make transatlantic harmonisation of standards difficult, but also undesirable from a consumer standpoint.

With regard to food and nutrition this divergence finds expression in the precautionary principle applied in the EU. In accordance with this, products and technologies can be regulatorily restricted for precautionary reasons even if there is no scientifically proven risk for consumers, on the grounds of basic uncertainty. Similarly in the EU, even if a product or mode of production is scientifically proven to be harmless, ‘non-scientific’ parameters, such as ethical considerations, can influence legislation. In the United States, by contrast, regulatory restrictions in the food sector are generally possible only if there is concrete evidence of health concerns. If consumers are ever harmed, however, the availability of class-action lawsuits provides them with an effective instrument for recourse claims (on this see Section 3.1.1).

A similar picture emerges with regard to drugs in respect of pricing and reimbursement practices. In the United States these are largely regulated by the market, while in the EU the individual member states are responsible, in accordance with the subsidiarity principle (Section 3.2.1.3).

There are also substantial differences in the regulatory philosophies applied to data protection. While in the EU protection of personal data is laid down in the Charter of Fundamental Rights and subject to statutory regulation, in the United States statutory provisions exist only on a sectoral basis, with much more reliance on the principle of self-regulation (Section 3.3).

Likewise, different market structures and legal frameworks underlie the market for financial services, which have led to differences in the progress of implementation and the focus of ongoing financial market reforms (Section 3.4).

Overall, the cited fundamental differences lead us to the conclusion that an approach based on the harmonisation of standards is not realistic or even desirable, assuming that the prevailing standards express the respective regulatory philosophies, market structures and popular preferences.

The next less stringent approaches to removing non-tariff trade barriers – equivalence or mutual recognition – should not be pursued in these areas either, because, in certain circumstances, they could have negative rather than positive effects on consumer welfare. For example, although the mutual recognition of standards in the food sector could lead to falling consumer prices in Europe, at the same time European requirements with regard to product safety or the right to information and the possibility of informed and responsible sustainable consumption would be curtailed (on this see Section 3.1.3). This line of argument applies equally to pricing and reimbursement practices with regard to drugs, as well as to data protection and financial services.

Thesis 2: In some areas, however, there are also substantial similarities with regard to regulatory approaches that should not be overlooked and in which harmonisation or mutual recognition of standards would make sense.

These significant differences in regulatory philosophies in some areas should not be generalised, however. There are other areas in which the regulatory approaches of the United States and the EU are similar and in which transatlantic harmo-

nisation of standards has considerable potential for consumer policy.

This is particularly the case with regard to the approval and marketing of drugs and medical products, in respect of which closer regulatory cooperation has the potential to increase consumer safety, improve the information situation for consumers and enhance their economic interests.

Thus the mutual recognition of GMP inspections and documents for the accreditation of generic drugs reduce approval and production expenditure for companies and thus may lead to falling end prices for consumers. Equally, harmonisation of approval procedures for biosimilars at EU level and the joint further development of harmonised ICH guidelines for medicinal products for paediatric use and a uniform transatlantic terminology would have a positive effect on general consumer safety (Section 3.2.1).

In the market for medical products harmonisation upwards to the US level with regard to approval requirements and transparency provisions could bring about an increase in consumer safety and information (Section 3.2.2).

Thesis 3: There is enormous consumer-policy potential in intensified exchange of information between the EU and the United States. This should be tapped within the framework of regulatory cooperation.

Our analysis has also shown that the consumer-policy potential of the TTIP negotiations is enormous even beyond the instruments of harmonisation, equivalence and mutual recognition. In particular, the structured and formalised exchange of information between governments and regulatory authorities, as well as joint initiatives, could give a decisive boost to consumer welfare. This includes the following measures in particular:

(I) Food and nutrition (Section 3.1.3)

- introduction of a transatlantic food early warning and traceability system;
- collaboration in combating antibiotic resistances;
- collaboration in combating (child) obesity.

(II) Drugs and medical products (Sections 3.2.1.3 and 3.2.2.3)

- intensified exchange of information, in particular between the EMA and the FDA and, in parallel, scientific consultations on the evaluation of drugs;
- enhanced exchange of information between authorities in the area of medical product labelling and identification, as well as risky products.

(III) Data flows and data protection (Section 3.3.3)

- exchange of information on developments and violations in the area of data protection, as well as joint law enforcement;
- intensified cooperation in the area of cyber-security.

(IV) Financial services (Section 3.4)

- exchange of information on the implementation of international financial services standards.

Thesis 4: The assumption that the level of consumer protection or regulatory approaches in the EU are fundamentally higher or better is not warranted.

From time to time the impression is given in the public debate that the level of consumer protection and the regulatory approaches in the EU are higher or better than those in the United States, across the board. As we have seen, this is not the case. In particular, our analysis of the market for medical products shows that US regulatory approaches in this area are ranked more highly by key stakeholders.

There are also examples in the food sector of 'higher' levels of consumer protection in the United States in certain areas. For example, the sale of raw milk and raw milk products is prohibited in some US states on health protection grounds (Section 3.1.1).

Likewise, the establishment of the Bureau of Consumer Financial Protection highlights the particular importance attached to consumer protection in financial services in the United States. There is still no authority of this kind in the EU.

In general, it follows that any assessment of the state of the TTIP negotiations must not be sweeping, but should always refer to specific markets.

Thesis 5: In order to tap the potential of regulatory cooperation minimum requirements have to be met.

Based on experience of international regulatory cooperation, various general requirements can be derived with regard to the transatlantic partnership that would have to be complied with if TTIP's potential is to be fully realised. Particular care must therefore be taken that regulatory cooperation:

- does not undermine basic democratic principles and the right of nation states to regulate themselves. Thus regulatory cooperation must lead to recommendations and drafts of norms and standards, but not intervene directly in legislative activities;
- is based on an unambiguous mandate that clearly regulates the rights and obligations of those involved;
- takes into consideration the positions of different stakeholders and does not favour any group of stakeholders over others. This stakeholder participation is particularly necessary in preparing the work plan, in impact assessment and in commenting on recommendations on specific issues.

Thesis 6: The TTIP negotiations have the potential to promote consumers' interests. However, in order to realise this potential a change of mentality is needed in the conduct of the negotiations.

The potentials of regulatory cooperation for consumers will be fully realised only if the current narrow focus is expanded to encompass a modern and broad understanding of consumer welfare. Decisive in this respect is that not only consumers' economic interests in obtaining goods on favourable terms be taken into consideration in the negotiations, but also their interests in safety, information, education and sustainable consumption (Section 2.3).

It follows from this that the impact assessments mentioned by the negotiators within the framework of transatlantic cooperation must not be limited to impact on trade (Fliegauf 2013), but must also include effects on consumer welfare (in the broad sense used in this study).

Furthermore, the success of the negotiations from the standpoint of European consumers will depend on the following factors:

- Harmonisation should take place only when the best regulatory approaches from a consumer standpoint are taken as a benchmark (Theses 1 and 2) and the existing regulatory philosophies do not differ from one another fundamentally. The instruments of equivalence and mutual recognition should be

applied only if the relevant regulatory goals are identical. They must not lead to market distortions or a 'race to the bottom'.

- In the negotiations the enormous potential in particular of intensified regulatory dialogue and closer cooperation should be raised (Thesis 3). However, minimum requirements must be imposed on regulatory cooperation (Thesis 5).

Even though the issue of transparency in the conduct of the negotiations is not a topic of the present study, the credibility of the negotiating partners and citizens' trust in them depends on the negotiating partners' learning from the mistakes of the past and nurturing a new culture of openness.

List of interviewees

Dr Alexander Beck

Director, Assoziation ökologischer Lebensmittelhersteller (Association of Organic Food Producers)

Ludwig Börger

European policy officer, German Farmers' Association – focus: livestock production

Dr Joachim Bühler

BITKOM, responsible for politics and business

Prof. Dr Josef Falke

University of Bremen, Project leader 'Handelsliberalisierung und Sozialregulierung in transnationalen Konstellationen' (Trade liberalisation and social regulation in transnational constellations)

Monique Goyens

BEUC, The European Consumer Organisation, Director General

Lutz Güllner

European Commission, Directorate General for Trade, Deputy Head of the Unit for Information, Communication and Civil Society

Dr Rainer Metz

Deputy departmental head, Federal Ministry of Justice and Consumer Protection

Dr Stormy-Annika Mildner

Head of Department of External Economic Policy, Bundesverband der Deutschen Industrie e.V. (Federation of German Industries)

Felix Neugart

Head of Department of Foreign Trade Promotion and Law, Deutscher Industrie- und Handelskammertag (Association of German Chambers of Commerce and Industry)

Helga Springeneer

Head of Department of Consumer Policy, Verbraucherzentrale Bundesverband e.V. (Federation of German Consumer Organisations)

Michael Weller

Head of Policy Department, GKV-Spitzenverband (Organisation of the National Association of Statutory Health Insurance Funds)

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