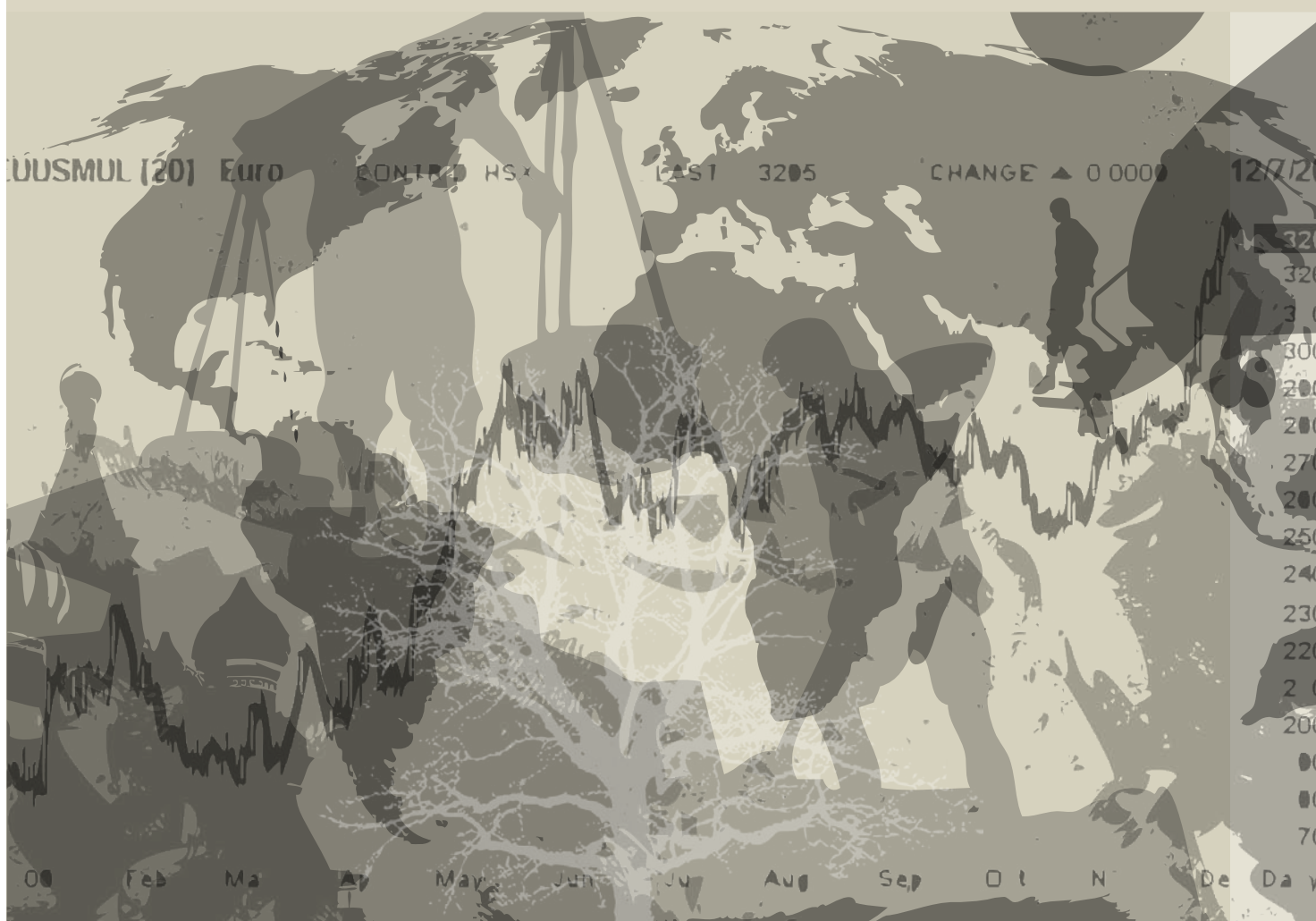


TTIP – regulatory cooperation on food and health issues

Frode Veggeland



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Visiting address: C.J. Hambros plass 2d
Address: P.O. Box 8159 Dep.
NO-0033 Oslo, Norway
Internet: www.nupi.no
E-mail: info@nupi.no
Fax: [+ 47] 22 99 40 50
Tel: [+ 47] 22 99 40 00

TTIP – regulatory cooperation on food and health issues

Frode Veggeland
University of Oslo/NIBIO

Abstract

This paper studies the TTIP negotiations on regulatory cooperation with an emphasis on food and health issues, in particular sanitary and phytosanitary measures (SPS measures). In order to put the current TTIP negotiations in context, the paper studies the history of the transatlantic regulatory cooperation going back to the 1990s. The paper includes assessments of some of the high-profiled disagreements and disputes between the EU and the U.S. on regulatory issues, such as the hormones case, the chlorinated poultry case and the case on GMOs – all dating back to the 1990s. The paper describes the role of mutual recognition of conformity assessment procedures and equivalence assessments of regulations and standards, as means to facilitate trade, and analyses what role these regulatory tools may play in TTIP. Some critical regulatory issues of the TTIP negotiations are highlighted including institutional issues, and some pitfalls and possibilities for regulatory cooperation on these issues are analysed. The paper discusses some potential consequences of a TTIP Agreement, including also the consequences for third-countries such as Norway. Key conclusions are as follows: As the TTIP negotiations now stand, there is little to indicate dramatic changes in EU and U.S. regulatory approaches. However, if the EU and the U.S. succeed in setting up a strong institutional framework for regulatory cooperation, based on stronger stakeholder involvement and effective dispute settlement mechanisms, TTIP could have more substantial long-term effects on regulatory developments.

Correspondence: frode.veggeland@medisin.uio.no

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Introduction

This paper is based on a study of the regulatory cooperation between the EU and the U.S. in the context of the negotiations on a Transatlantic Trade and Investment Partnership (TTIP), which was launched in 2013. The study does not cover all regulatory sectors, but is focused on food and health issues.¹ However, for the need of limiting the scope of the paper, not all health-related areas are included. For example, areas such as occupational safety and chemicals are not discussed. However, SPS measures (see definition in Appendix 2) have been given a prominent place mainly because these measures touch upon issues of high political and public concern (see below). The paper also discusses some key horizontal regulatory issues, i.e. issues which are relevant across sectors.

The aim of the study is threefold. One is to understand the context of the TTIP negotiations by studying the historical path of the transatlantic regulatory cooperative framework from the 1990s up until the current TTIP negotiations. Another aim is to increase the understanding of the mechanisms involved in the regulatory cooperation. This is done by studying regulatory issues at stake and the tools used by the EU and the U.S. in their attempts to avoid that diverging technical regulations and standards have trade-restricting effects. Technical regulations refer to measures where compliance is mandatory whereas standards refer to rules, guidelines etc. where compliance is not mandatory (c.f. Appendix 2). Both technical regulations and standards may in effect involve trade-restrictive measures and both are subsequently important part of multilateral and bilateral trade negotiations, including the TTIP negotiations. The third aim of this paper is to assess some of the consequences of a possible TTIP Agreement for transatlantic regulatory cooperation. Included in these assessments is an evaluation of challenges facing third-countries, in particular EEA (European Economic Area) countries that are not members of the EU (Norway, Iceland and Liechtenstein). These countries are well integrated in the EU's internal market, but not part of the TTIP negotiations.

¹ For the need of limiting the scope of the paper, not all health-related areas are included. For example, areas such as occupational safety and chemicals are not discussed. However, SPS measures (see definition in Appendix 2) have been given a prominent place, mainly because these measures touch upon issues of high political and public concern (see below).

The ambition of the paper is thus to place the TTIP negotiations in a historical context and to analyse the consequences of a possible TTIP agreement based on this context. The data used for the study are: public documents, press releases, position papers, TTIP negotiation documents, and interviews with interest groups and government officials of the EU, the U.S. and Norway (see Appendix 1).

Background: world trade and non-tariff measures

Trade barriers caused by regulatory differences (Non-Tariff Barriers to Trade) between the EU and the U.S. have persisted over a long time, even when traditional barriers such as tariffs, have declined (Josling and Tangermann 2015; Veggeland and Evensen 2015). Non-Tariff Barriers to Trade (NTBs) refer to a large number of trade restrictions (other than tariffs) that emanate from domestic measures such as health and sanitary standards, production methods requirements, documentation requirements, procedures and requirements at the border etc. that make importation or exportation of goods and services difficult and/or costly (Josling et al. 2004; Fliess and Kim 2008; Van den Bossche and Zdouc 2013).

NTBs may thus involve a large variety of sectors, policies and specific technical regulations and standards. This paper does not cover all regulatory sectors, but focuses in particular on those regulations and standards that are related to food and health. Much attention is drawn towards so-called sanitary and phytosanitary measures (SPS measures), which are measures used to protect human, animal and plant life or health and to ensure food safety, including also to prevent the spread of pests (Appendix 2). SPS measures have been given much attention in transatlantic relations, not least because of several high-profiled trade disputes, such as the cases of hormones in beef, chlorinated poultry and genetically modified organisms (GMOs), which have taken place within the World Trade Organization's dispute settlement system (see below). In fact, ever since the 1990s, food and health policies have been at centre stage in conflicts on NTBs arising in transatlantic relations (Petersmann and Pollack 2003; Josling et al 2004; Johnson 2015; Josling and Tangermann 2015; Veggeland and Evensen 2015). In this context, one of the crucial concerns have been how to find ways of facilitating trade without compromising legitimate objectives such as health protection. These concerns have been discussed intensively within the framework of the transatlantic cooperation ever since the EU-US disputes on food and health related issues started to appear after the WTO was established in 1995. Thus, the efforts of the EU and the U.S. to find ways of reducing the problem

of NTBs in their transatlantic economic relations started long before the launching of the TTIP negotiations in 2013.

A study commissioned by the European Commission found in 2009 that there were substantial economic benefits to be reaped from reducing trade costs of regulatory divergences in the transatlantic economic relations (Ecorys 2009). The study found that EU-benefits from eliminating NTBs would primarily come from trade in motor vehicles, chemicals, pharmaceuticals, food and electrical machinery, whereas U.S.-benefits would primarily come from electrical machinery, chemicals, pharmaceuticals, financial services and insurance sectors (ibid.). Regulatory convergence has thus been stipulated as one of the key objectives of trade discussions taking place within the EU-U.S. transatlantic partnership and was subsequently put high on the agenda in the TTIP negotiations.

Regulatory cooperation and international agreements

In a trade setting, the aim of regulatory cooperation is to abolish or reduce the regulatory differences that create trade barriers. This can be achieved by regulatory harmonization, i.e. where regulations and standards are developed to be uniform across participating authorities, or it can be achieved through regulatory convergence, whereby the cooperating partners enter into a more long-term process using a variety of means to gradually make regulatory requirements more similar or “aligned”. Such means may include both “soft” and “hard” regulatory tools as described below. Thus, regulatory cooperation normally implies a long-term process in which the cooperating partners seek to identify areas where convergence can be gradually achieved.

As indicated, regulatory cooperation may incorporate a broad range of activities, both “hard” means of regulation, such as harmonization of regulatory approaches and standards and adoption of binding agreements, and “soft” means of regulation, such as information exchanges, dialogues among regulators, and exchange of personnel, designed to build trust and confidence (Ahearn 2009; Elvestad and Veggeland 2010; Josling and Tangermann 2015; Regulatory Studies Center 2016). The more different the regulatory systems are, the more important such trust and confidence building activities become. Regulatory cooperation, in particular when involving harmonization, is

further complicated by the fact that regulatory sovereignty and autonomy can be challenged, i.e. the right to decide on the appropriate levels of protection or other legitimate concerns that regulations and standards are expected to achieve, and the right to decide on the suitable means to address these concerns (Martinez-Fraga and Reetz 2015).

Regulations and standards are often designed to protect what is considered to be basic national concerns. When such concerns are at stake, it seems very hard to make much progress in regulatory cooperation. We may for example observe this in the long-standing regulatory disputes between the EU and the U.S. on hormones and chlorinated poultry (see below). Thus, regulatory harmonization, and even far-reaching convergence, is most likely to take place with regard to non-controversial measures – those that are not considered to challenge basic national concerns. Nevertheless, studies show that substantial economic benefits can be achieved through trade facilitation even on such less controversial regulatory areas (Ecorys 2009; Veggeland and Evensen 2015).

There are the two WTO agreements, which are particularly relevant for trade-related regulations and standards: the WTO's SPS Agreement (Agreement on Sanitary and Phytosanitary measures) and the TBT Agreement (Agreement on Technical Barriers to trade). In the TTIP negotiations on regulatory cooperation it is stated that the cooperation will be based on these two agreements.

The SPS Agreement “applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade” (SPS Agreement Article 1). SPS measures are moreover defined as any measures used to protect human, animal and plant life or health (Appendix 2). Measures implemented to ensure food safety is thus at the core of what is covered by the agreement. The agreement entered into force simultaneously with the establishment of the WTO – on 1 January 1995. The SPS Agreement thus gives WTO members the right to impose what is in effect trade restrictions, but under certain specified conditions. A basic requirement is that the (trade-restricting) measure needs to be based on science.

The TBT Agreement covers “...all products, including industrial and agricultural products...”, but “...do not apply to sanitary and phytosanitary measures” (Article 1), as specified in the SPS Agreement.

The TBT Agreement states that regulations and standards “...shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create...” (Article 2) (see also Appendix 2). Some of legitimate objectives listed are prevention of deceptive practices and protection of human health or safety, animal or plant life or health, or the environment.

Both the SPS and TBT agreements state that the obligations of the agreements can be met by basing national measures on recognized international standards. The agreements specify a number of instruments that can be used to avoid and/or remove NTBs: *harmonization* (SPS Agreement Article 3, TBT Agreement Article 2 and Article 5), *mutual recognition of conformity assessment* (TBT Agreement Article 6) and *equivalence* (SPS Agreement Article 4).² As discussed in more detail below, the EU and the U.S. also aim to incorporate the regulatory cooperative work taking place within the frameworks of the EU-U.S. VEA of 1998 with later revisions, and the EC-U.S. MRAs of 1999 and 2004 in a possible TTIP agreement (USDA Foreign Agricultural Service 2005; 2010; United States Trade Representative 2014; Veggeland and Evensen 2015; Puccio 2016).

² These instruments are described in more detail under the headline “TTIP and regulatory tools used to facilitate trade”.

Transatlantic regulatory cooperation

The transatlantic regulatory cooperation framework dates back to the early 1990s, when the European Commission's DG Internal Market (now DG Enterprise) started working with its U.S. counterparts to promote cooperation, in particular focusing on barriers and costs for businesses stemming from regulatory differences (Vogel and Swinnen 2011). In May 1998, the Transatlantic Economic Partnership (TEP) was launched. TEP was created in order to give new impetus to EU-U.S. co-operation in the field of trade and investment. A core bilateral element of TEP was to tackle the problem of regulatory barriers, which was seen as the main obstacle to transatlantic business. The EU and the U.S. also had the intention of integrating labour, business, and environmental and consumer issues into the cooperation process. Thus, transatlantic regulatory cooperation was intended to be at the core of TEP.

The EU and the U.S. realized that diverging regulations or duplicative requirements, such as testing and conformity assessment, often cause unnecessary trade barriers and high costs for companies thus potentially affecting both trade and economy negatively. Two early results of the EU-U.S. regulatory cooperation were the EU-U.S. Veterinary Equivalence Agreement (VEA), signed in 1998, and the EC-U.S. Mutual Recognition Agreement (MRA) signed in 1999 (Official Journal of the European Communities 1998, 1999). However, none of these agreements have been unconditional successes. The agreements have been hard both to implement and to maintain fully operative – the VEA, although operational and considered to have legal status by the EU, didn't even become a fully binding agreement as it was never approved and ratified by the U.S. Congress (Elvestad and Veggeland 2004, 2005; USDA Foreign Agricultural Service 2005, 2010; Veggeland 2006; Ahearn 2009; United States Trade Representative 2014; Kommerskollegium 2015; Veggeland and Evensen 2015). However, based on the

regulatory cooperation within TEP, the EU and the U.S negotiated another MRA (on marine equipment), which entered into force in 2004, and is still operational (Elvestad and Veggeland 2004; Official Journal of the European Union 2004).

In 2005, the High Level Regulatory Cooperation Forum (HLRCF) was established. The forum allowed senior officials from all areas of government of the EU and the U.S. to exchange information, discuss regulatory perspectives, and promote regulatory cooperation. Thus, emphasis was put on so-called “soft governance”, i.e. non-binding forms of cooperation (Elvestad and Veggeland 2010). The Forum provided an important arena where opportunities for cooperation on specific sectorial issues could be identified. Moreover, stakeholders have been engaged in public sessions taking place within regular meetings of the Forum.

In 2007, the Transatlantic Economic Council (TEC) was established, functioning as an arena for political representatives to engage with stakeholders with the aim of deepening regulatory cooperation between the EU and the U.S. In the EU in 2011, DG Trade took over the responsibility to manage the TEC from DG Enterprise. After the launch of the TTIP negotiations, the TEC has only pursued its cooperation at technical levels. Thus, the political discussions of the transatlantic regulatory cooperation are currently taking place within the TTIP setting. Moreover, the two Parties have indicated that core elements of the EU-U.S. VEA, as well as the MRAs will be included in a TTIP Agreement.

TTIP and regulatory tools used to facilitate trade

Regulatory dialogue: As already indicated, TTIP builds on the established framework for transatlantic regulatory dialogue (Vogel and Swinnen 2011), but the Parties aim at making the framework more comprehensive (c.f. coverage, institutional mechanisms). The regulatory dialogue may potentially continue on its own terms independently of TTIP, primarily emphasizing “soft” means of cooperation, such as dialogue and information exchange. Alternatively, it may include the use of some or all of the regulatory tools described below: harmonization, mutual recognition and equivalence.

Harmonization: Based on available documents and texts and statements from EU and U.S. officials, TTIP will not go far on harmonization – neither regulatory goals nor appropriate levels of protection, are said to be substantially changed by the Parties as a consequence of the negotiations (see also Appendix 1). On both sides, officials clearly state that harmonization will not be pursued for most parts of the regulatory area, and in particular not for those areas involving basic and fundamental concerns, such as health and environmental protection. The EU and the U.S. both emphasize the importance of upholding their right to set their own standards (c.f. regulatory sovereignty). However, by identifying common ground through the negotiations, harmonization in some sectors may of course take place, for example as means of simplifying procedures and reducing red-tape in technical and non-controversial areas.

Mutual recognition: Mutual recognition regimes have been described in the following way:

Mutual recognition regimes set the conditions governing the recognition of the validity of foreign laws, regulations, standards, and certification procedures among states in order to assure host country regulatory officials and citizens that their application within their borders is “compatible” with their own, and that incoming products and services are safe. These conditions involve different types of obligations for *home states*, who benefit from conditional recognition of the laws and regulations applicable to products, persons, firms and services, and *host states*, who forego the application of their own rules to products, persons, firms and services, provided that the agreed conditions are met. (Nicolaodis and Shaffer 2005: 264).

Mutual recognition agreements (MRAs) are thus aimed at benefiting industries by providing easier market access – primarily through mutual recognition of conformity assessment procedures (Shaffer 2003; Elvestad and Veggeland 2004, 2005; Nicolaodis and Shaffer 2005). MRAs lay down the conditions under which one Party will accept conformity assessment results (e.g. testing, certification etc.) performed by the other's Party designated conformity assessment bodies (CABs) to show compliance with the first Party's requirements and vice versa. MRAs include lists of designated laboratories, inspection bodies and conformity assessment bodies in both the exporting and the importing country. MRAs may facilitate trade and lower costs (time and money) caused by duplication of procedures for testing, certification, product approvals, etc. MRAs have so far not been used much for specific product regulations or standards. Instead, product approvals are most often made on the basis of the importing country's regulatory regime (c.f. the exporting country approves products produced according to the importing country's rules).

Mutual recognition of conformity assessment may thus improve market access by removing NTBs. In fact, when the U.S. government entered into negotiations with the EU in the late 1990s on a comprehensive MRA including six sector annexes, it estimated that the package, which covered about \$47 billion worth of trade, would eliminate costs equivalent to two or three percentage points of tariffs (United States Trade Representative 1997). The MRA was subsequently concluded in 1999. Article 2 specifies the purpose of the Agreement (Official Journal of the European Union 1999):

This Agreement specifies the conditions by which each Party will accept or recognise results of conformity assessment procedures, produced by the other Party's conformity assessment bodies or authorities, in assessing conformity to the importing Party's requirements, as specified on a sector-specific basis in the Sectoral Annexes, and to provide for other related cooperative activities. The objective of such mutual recognition is to provide effective market access throughout the territories of the Parties with regard to conformity assessment for all products covered under this Agreement. If any obstacles to such access arise, consultations will promptly be held. In the absence of a satisfactory outcome of such consultations, the Party alleging its market access has been denied, may, within 90 days of such consultation, invoke its right to terminate the Agreement in accordance with Article 21.

The agreement covers six product sectors: *Telecommunication Equipment*, *Electromagnetic Compatibility (EMC)*, Electrical Safety, Recreational Craft, Pharmaceutical Good Manufacturing Practices (GMPs), and Medical Devices. In fact, only the two first of these sector annexes (set in italics above) became operational thus illustrating the problem of facilitating trade through regulatory cooperation. However, the EU and the U.S. have nevertheless negotiated an additional MRA under the Transatlantic Economic Partnership – the MRA on marine equipment (Elvestad and Veggeland 2004). This MRA covers mutual recognition of conformity assessment on a number of marine equipment products listed in Annex II of the agreement. Moreover, the MRA also includes a provision (Article 4) on equivalence of technical regulations. The negotiations began in late 1999 and were concluded in June 2003, and the agreement was signed on 27 February 2004 and entered into force on 1 July that same year (Official Journal of the European Communities 2004). A parallel MRA has been negotiated between the U.S. and the three EFTA countries Norway, Iceland and Liechtenstein, which are part of the Agreement on the European Economic Area (EEA Agreement) and thus have access to the EU's internal market. This parallel MRA was negotiated according to Protocol 12 (*On Conformity Assessment Agreements with Third Countries*) of the EEA Agreement, was signed on 17 October 2005, and became effective on 1 March 2006.

As illustrated above, there are some examples of the EU and the U.S. having established successful MRAs, but the results are all in all considered to be far below the initial ambitions. TTIP aims to overcome the problems of maintaining effective MRAs and thus to facilitate trade more than what has been achieved by the established MRAs. One way of ensuring this is to set up more effective systems for management and dispute settlement. Attempts at this are reflected in the TTIP proposals on institutional issues (see Appendix 1 and below). If the EU and the U.S. succeed in establishing efficient mutual recognition under TTIP, business in these territories may end up with a competitive advantage on two of the clearly most important markets in the world. This in turn, will be a challenge for third countries with an interest in access to these markets.

Equivalence assessments: Determination of equivalence means that trading parties accept rules that are different as long as it is possible to determine that the rules fulfil some commonly stated objective in a satisfactory way (Elvestad and Veggeland 2004; 2005; Veggeland 2006). Equivalence assessments can be done for both individual product regulations and standards (e.g. labelling rules) and for regulation of inspection and control systems. Equivalence is an

integrated part of the EU-U.S. Veterinary Equivalence Agreement (VEA) of 1998, and TTIP aims at continuing and expanding the use of equivalence as a trade-facilitating tool in the transatlantic regulatory cooperation. Article 1 of the VEA clearly emphasizes the use of equivalence to facilitate trade:

The objective of this Agreement is to facilitate trade in live animals and animal products between the Community and the USA by establishing a mechanism for the recognition of equivalence of sanitary measures maintained by a Party consistent with the protection of public and animal health, and to improve communication and cooperation on sanitary measures.

The scope of the Agreement is stated in Article 3:

(...) initially be limited to the sanitary measures applied by either Party to the live animals and animal products listed in Annex I, except as provided for in paragraph

(...) this Agreement shall not apply to sanitary measures related to food additives, processing aids, flavours, colour additives, sanitary stamps, irradiation (ionisation), contaminants (including pesticides, chemical residues, mycotoxins, natural toxins, physical contaminants and animal drug residues), chemicals originating from the migration of substances from packaging materials; labelling of foodstuffs (including nutritional labelling); feed additives, animal feeding stuffs, medicated feeds and premixes.

The VEA thus excludes a number of areas from the equivalence assessments, including the phytosanitary (c.f. plant health) area. The Parties have indicated that the VEA (similar to what is done in the Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada) will be included as part of the SPS chapter in a TTIP Agreement. However, the scope will probably be expanded, in accordance with the EU proposals (see Appendix 1) and the discussions that have been taking place in the TTIP negotiations on the SPS Chapter (interviews; Puccio 2016). One challenge for achieving and maintaining effective equivalence agreements is the difference in approach on which the EU and U.S. regulatory systems are based. The EU has adopted an approach – “from farm to fork” – where emphasis is made on inspection and control throughout the production chain, identifying critical points with regard to risks for human health (c.f. HACCP); the US also focus on critical points, but has more emphasis on end-product control (Van Zwanenberg and Millstone 2005; Johnson and Hanrahan 2010; Johnson 2015; Moyens 2015).

The EU and the U.S. regulatory systems are also different in the sense that the EU has put in place a more integrated approach where

responsibilities for human, animal and plant health protection is placed within one single agency (DG Santé), whereas the U.S. has delegated responsibilities and authority to a number of agencies (see also below) (Ugland and Veggeland 2006; Veggeland and Evensen 2015). Such differences in regulatory approach and culture create barriers towards the convergence of national regulations and standards across borders, and moreover put clear limits on how much can be achieved through trade-facilitating tools such as harmonization, equivalence and mutual recognition (Echols 2001; Veggeland 2006; Ahearn 2009; Josling and Tangermann 2015; Veggeland and Evensen 2015). Differences in the role of stakeholders, consumer concerns and the use of the precautionary principle are also part of this discourse (see below).

TTIP – key issues regarding food and health regulation

Wider coverage, but limited harmonization

The submitted TTIP proposals suggest that a TTIP agreement will end with a wider coverage on regulatory issues than the already established bilateral agreements (Appendix 1). The sector-specific chapters of TTIP were actually planned to cover nine sectors beyond the SPS area: cars, chemicals, pharmaceutical, medical devices, cosmetics, textiles, ICT, engineering and pesticides (compared to the six sectors covered by the MRA). In addition, submitted proposals to the SPS chapter included a number of areas, which are not part of the VEA, such as phytosanitary measures, animal welfare (EU proposal), anti-microbial resistance (EU proposal), risk and science (U.S. proposal) and approval of products of modern agricultural technology (U.S. proposal) (Puccio 2016; interviews; Appendix 1). However, negotiations have shown that the U.S. does not want animal welfare (not considered a SPS issue), nor anti-microbial resistance (not considered a trade issue) to be part of a final agreement. The EU does not want provisions on risk and science and approval of products of modern agricultural technology along those lines stipulated by the U.S. as the U.S. proposals on these areas are considered to challenge the EU's regulatory system (*ibid.*). There is, in fact, nothing in the available documentation (including interviews) to indicate that harmonization or regulatory convergence in controversial areas (e.g. chlorinated poultry, hormones, GMO etc.) will be part of a final agreement. For example, the European Commission has ruled out any EU proposal concerning GMOs (c.f. the U.S. proposal on modern agricultural technology) (European Parliament 2016a). However, the scope of the TTIP will be broader than earlier agreements, comprising among other things, new sectors (as indicated above), a wider scope for future regulatory cooperation, and, maybe most importantly, a new set of management and dispute settlement mechanisms, which may dedicate the Parties more firmly to regulatory cooperation, as well as to contribute to more effective implementation of and compliance with an agreement (Puccio 2016) (see also below). Moreover, both Parties will of course make an effort to remove NTBs, through equivalence, mutual recognition and harmonization, in areas which *do not* challenge the autonomy to decide on appropriate levels of protection, i.e. do not seriously challenge regulatory sovereignty.

TTIP negotiations – disagreements and developments

Up until the mid-2016 the TTIP negotiations on the SPS and TBT areas were slow (Puccio 2016). Some issues on the agenda seemed to be very hard or even impossible to bring into a final agreement (e.g. animal welfare, GMOs), other issues were progressing relatively well, such as discussions on phytosanitary measures, and some issues remained difficult, but manageable. One issue, where disagreement remained concerned ‘zoning’ (or ‘regionalization’), which relates to the management of situations where there, e.g., is an outbreak of animal disease in a specific area of a country, whereas a large part of the country is unaffected (ibid.). The main question of interest here is whether the country (automatically) should be subject to import restrictions, or whether restrictions should only apply to the specific area concerned. Moreover, how can “safe areas” become separated from “contaminated zones” in such situations? The U.S. follows a strictly scientific approach, which means that regions are considered “safe” based on their related propensity to develop a certain regulated organism of sanitary and phytosanitary concern (ibid.). The EU has suggested that the term “protected zone” should apply to any geographical area in the EU in which that organism is not established in spite of favourable conditions of concern and the fact that the organism of concern is present in other parts of the EU. The Parties seem to seek a solution to this divergence in available internationally agreed guidelines (ibid.; interviews).

Another area of disagreement was based on the U.S. proposal for including in the SPS chapter a provision on risk and science (ibid.). This is a major U.S. priority and has been subject to discussions between the EU and the U.S. for many years, e.g. in the discussions on principles for risk analysis taking place within the FAO/WHO standardization body Codex Alimentarius Commission (Veggeland 2002a; Veggeland and Borgen 2005). The EU has a different approach to risk management and risk assessment than the U.S. Relevant in this context is the choice of which “other legitimate factors” (such as consumer expectations and societal, ethical, or environmental concerns) to take into account in a risk management decision besides health protection/safety, how uncertainty from scientific results or insufficient studies on a particular risk is managed, and the application of the precautionary principle (see below).

Thus, disagreements between the EU and the U.S. are more about different *approaches* to regulation than about whether to harmonize established regulations and standards or not. Both Parties are reluctant to agree on changes, which fundamentally may alter their established regulatory systems and approaches. The TTIP discussions between the

EU and the U.S are thus affected and complicated by continuing regulatory differences and disagreements. Still, developments in the negotiations in late 2016 seemed to indicate that discussions on regulatory issues progressed relatively well. In fact, after the negotiation meeting in October 2016, regulatory issues were not considered to be the most difficult area where mutually agreed solutions could be found (interviews). One important reason for this progress was that controversial issues, such as hormones, chlorinated poultry, and GMOs, were excluded from real and substantial negotiations between the Parties.

Two non-SPS areas being negotiated in TTIP are clearly also related to health regulation: pharmaceuticals and medical device. Both these areas were part of the EC-U.S. MRA of 1999, but neither of the relevant sector annexes were made operational. Thus, TTIP aims at realizing the goals of the MRA to achieve effective regulatory cooperation on pharmaceuticals and medical device in order to facilitate trade. The TTIP proposals include primarily “soft” forms of cooperation through exchange of information and best practices among regulators (including confidential information and trade secrets), parallel scientific advice by the European Medicines Agency and the U.S. Food and Drug Administration on authorisation of paediatric medicines; exchange of information on common standards for unique identifiers and cooperation and other activities in international cooperation (European Parliament 2016a; Puccio 2016; interviews; Annex 1). Moreover, the EU also proposes joint participation in the information-sharing pilot on generic medicines within the International Generic Drug Regulatory Programme. There are also discussions on establishing a new MRA, i.e. mutual recognition on good manufacturing practice (GMP) inspections in the pharmaceutical area (*ibid.*). Included in the discussions are also elements of harmonisation, e.g. harmonisation of requirements for clinical data for complex generic medicines – requiring performance of pre-clinical tests and trials for their authorisation. The EU has also proposed that regulatory cooperation on medical devices should include exchange of information and best practices, e.g. exchange of information on the state of play of EU legislation on medical devices and on *in vitro* regulation (*ibid.*). Elements of harmonisation to be discussed are compatibility and interoperability of the EU and U.S. database for Unique Device Identification, and alignment with international standards (*ibid.*).

The proposals on trade-related aspects of Intellectual Property Rights (IPRs) (c.f. patents, copyrights, trademarks etc.), have not been far-reaching, i.e. they only focus on a limited number of issues (Annex

1). The possible exception to this is the protection of geographical indications (GIs), which is considered by the EU as important in order to regulate and protect the trade interests of its food industries (ibid 1; interviews). In fact, GIs did become an important part of the recently completed CETA (Comprehensive Economic and Trade Agreement) between Canada and the EU. Another factor to take into consideration regarding IPRs is the question of how to involve stakeholders in the regulatory process. How stakeholders' involvement will be set up could be important, not least because of what is considered to be strong influence of pharmaceutical industries in the U.S. IPR regulation (Sell 2010).

What about hormones, chlorinated poultry and GMOs in TTIP?

These three issues have been on top of the agenda of many of the NGOs and other political organizations criticizing TTIP (see e.g. BEUC 2014, 2015; Greenpeace 2016). The assumption that the EU's strict rules on GMOs, chlorinated poultry and use of hormones in meat production, will be adapted to the more liberal rules of the U.S. as a consequence of TTIP, has been used by activists in Europe as illustrations and symbols of how TTIP will lower standards, favour business, and ignore consumer concerns. However, as clearly indicated by Commissioner for Trade, Cecilia Malmström, these issues are really not on the table in TTIP negotiations, as they fall under what she calls the "non-negotiable red lines" (Malmström 2016). Moreover, all three issues have actually been subject to formal disputes in the WTO, based on the EU's dedication to keep its disputed (trade-restricting) rules in place (European Parliament 2013).³ As stated in a Brief from the European Parliament:

The ongoing poultry dispute, as well as the earlier beef and GMO disputes, highlight the significant divergence in understandings of scientific evidence, scientifically proven risk and the precautionary principle between the US and EU (European Parliament 2013).

So what are these three issues really about?

The disagreement between the EU and the U.S. "on the placing on the market and the importation of meat and meat products treated with certain hormones" dates back to the 1980s and is one of the most well-known disputes disrupting transatlantic trade. The baseline of the

³ The formal documents from the WTO disputes are found at the homepage of the WTO (WTO 2016).

dispute is the EU ban against the use of hormones in meat production, which in effect has resulted in an import ban against other countries, such as the U.S., if a guarantee for hormone-free meat cannot be made. The import ban has seriously disrupted trade in meat between the EU and the U.S. (Veggeland and Evensen 2015).

The case was subject to a WTO dispute initiated by the U.S. in 1996 (Veggeland 2001; Bermann 2007; Johnson and Hanrahan 2010; Peel 2012). One of the core conclusions from the WTO legal bodies (Panel, Appellate body) was that the EU should lift its ban because it was not sufficiently justified by science (*ibid.*). The EU nevertheless chose to keep its ban in place. However, the conflict was temporarily resolved in 2008. On 25 September that year the EU and the U.S. notified the WTO's Dispute Settlement Body that they had agreed on a Memorandum of Understanding (MoU) regarding the importation of beef from animals *not treated* with certain growth-promoting hormones and the increased duties applied by the U.S. on certain EU products (United States Trade Representative 2008; Veggeland and Evensen 2015). Under the terms of the MoU, the EU accepted to provide significant access to U.S. produced beef from cattle not treated with growth-promoting hormones (first year up to 20.000 tons at zero duty – with the potential to increase to 45.000 tons in the fourth year). The U.S. agreed on its side to delay the imposition of additional duties on EU produce, which had been scheduled to go into effect prior to the MoU. The MoU has allowed for a sharp increase in exports of meat from the U.S to the EU thus clearly reducing the tension and damage to U.S. industry caused by the EU's ban. The MoU has later been revised and extended and the dispute is still in 2016 considered to be temporarily solved, even though the MoU does not exclude the possibility of a dispute on this topic to reappear (WTO 2014; European Commission 2015b; interviews). Thus, following the state of play in the WTO dispute on hormones (and following statements from the two Parties), the question of relaxing the EU's ban on hormone-treated meat will not be negotiated within the TTIP framework.⁴

The core issue of the transatlantic disagreement on chlorinated poultry is that the U.S. allows for poultry being processed with certain pathogen reduction treatments (PRTs) – such as chlorine dioxide – to ensure food safety, but the EU does not (United States Trade Representative 2014; Johnson 2015; Veggeland and Evensen 2015). The VEA from 1998 was originally supposed to solve the problem by

⁴ This is further documented by statements from both European Commission officials and U.S officials (interviews, Brussels, October 2016).

including poultry as a product category destined for equivalence, but the EU continued to prohibit the use of PRTs and thus the importation of poultry from the U.S. treated with these substances (ibid.). Based on scientific opinions stating that the pathogen reduction treatments in question were safe, the European Commission proposed to lift the import ban in 2008. The proposal was however rejected by the member states.

In January 2009 the U.S. filed a WTO complaint against the EU on this issue (ibid.). A WTO Panel was established, but the case was put on hold pending further consultations between the parties. Later, in 2014, the European Food Safety Authority's Panel on Biological Hazards (BIOHAZ)⁵ issued a "Scientific Opinion on the evaluation of the safety and efficacy of peroxyacetic acid solutions for reduction of pathogens on poultry carcasses and meat", which actually concluded that the pathogen reduction treatments were safe. This opinion may provide a scientific justification for a future authorization of the use of such treatments. However, the EU has nevertheless kept in place its ban on using chlorine as a substance to treat poultry. Moreover, the Commissioner for Health, Vytenis Andriukaitis, stated as late as in May 2016 that EU acceptance of chlorinated poultry is not relevant for discussions in the TTIP negotiations (European Parliament 2016b):

In relation to antimicrobial treatments of meat or carcasses, the EU allows for the approval of such treatments, provided that they are considered safe by the European Food Safety Authority (EFSA). In particular, they must only be used under strict conditions, fully respecting the stringent hygiene requirements that Union legislation requires to be applied all along the food chain process.

No antimicrobial treatments will be approved in the EU unless there is a clear scientific assessment confirming that they are beneficial for consumers (i.e. reduction of microbial contamination and reduction of safety risks). The Commission will not authorize the use of antimicrobial treatments as a replacement for hygiene practices but only as an additional tool to enhance the safety of the final product.

⁵ The following independent scientific experts were members of the Panel when the scientific opinion was issued: Olivier Androletti, Dorte Lau Baggesen, Declan Bolton, Patrick Butaye, Paul Cook, Robert Davies, Pablo S. Fernandez Escamez, John Griffin, Tine Hald, Arie Havelaar, Kostas Koutsoumanis, Roland Lindqvist, James McLauchlin, Truls Nesbakken, Miguel Prieto Maradona, Antonia Ricci, Giuseppe Ru, Moez Sanaa, Marion Simmons, John Sofos and John Threlfall.

There is currently no application for the approval of chlorine as a substance to treat poultry carcasses and no discussion on the acceptance of chlorinated chicken in the EU as a result of the negotiations of the Transatlantic Trade and Investment Partnership.

The U.S. poultry industry has indicated that it is unlikely to support a TTIP agreement if it does not provide better access for U.S. poultry products to the EU market (Johnson 2015:6). However, the European Commission, based on the positions of the European Parliament and the member states, has been clear and consistent in the TTIP negotiations on its defence of the ban on poultry processed with the disputed chemical substances. In February 2014, Ignacio Garcia Berceo, EU's chief TTIP negotiator, stated that the EU's strict regime for control of chemical substances would not be altered, as “mutual recognition” of safety standards only applies when the standards are “compatible (European Observer 2014). Thus, it seems clear that facilitation of EU-U.S. trade in poultry within the TTIP framework has to be achieved by other means than relaxing EU rules on pathogen reduction treatments. However, the firm current position of the EU in the TTIP negotiations does not of course rule out the possibility that the EU will change its rules on pathogen reduction treatments in the future. However, such changes seem to depend primarily on potential changes in the current positions of the European parliament and the member states – and not on the TTIP negotiations. It is also important to stress that the EU-U.S. conflict over chlorinated poultry is an old conflict, which has been pending unsolved ever since the 1990s and which will probably prevail in the future transatlantic economic relations whether a TTIP agreement materializes or not.

The differences in the EU and U.S. approaches to GMOs have a long history, and the case of GMOs has, similar to the hormones case and the chlorinated poultry case, been subject to trade conflicts, including the use of WTO's dispute settlement mechanisms. The WTO dispute concerning GMOs was based on certain EU measures on the approval of biotech products, which according to the U.S. government restricted imports of agricultural and food products from the U.S. (Suppan 2005). The EU moratorium specifying these measures, was put in place in October 1998 (the Moratorium was later replaced by other restrictive measures). The EU rules allow for product-specific safeguard measures against GMOs being implemented by member states. The U.S. (joined by Argentina and Canada) filed a WTO complaint against the EU on 13 May 2003. At this point in time, the U.S. claimed that the EU had not approved a new GMO crop since 1996 (*ibid.*: 5). Two fundamental and interrelated issues of this conflict can be identified: First, the EU's more restrictive approach to the approval of biotech products/GMOs –

causing injury to U.S exports of such products to the EU, and second, the EU's regulatory system for GMOs which allows for the use of the precautionary principle to protect consumer, animal and/or plant health and the environment in situations where scientific evidence is insufficient to assess the risks of biotech products.

The dispute on GMOs thus illustrates some core differences between the EU and U.S. regulatory systems with regard to the role of science, risk and precaution. The WTO panel issued its report in 2006 and pointed there to inconsistencies between the EU moratorium and approval procedures for GMOs, and the SPS Agreement. The Panel moreover concluded that many product-specific safeguard measures against GMOs, which had been implemented by member states, were neither based on satisfactory risk assessments nor could be justified as provisional safeguard measures under Article 5.7 of the SPS Agreement (which specifies the requirements for measures to be made in cases where relevant scientific evidence is insufficient) (*ibid.*). The EU later notified the WTO that its parallel GMO disputes with Canada and Argentina had been settled (in 2009 and 2010 respectively) by establishing and formalizing bilateral dialogues on issues related to the application of biotechnology to agriculture. However, as of 2016 a similar solution had not yet been found in the EU-U.S. dispute.

Thus, the EU's regulatory system for approval of GMO's has for a long time been put under pressure – not least from U.S. industries exporting biotech products. A restrictive EU system for approval of biotech products has nevertheless been kept in place so far. Moreover, as indicated above, in the TTIP negotiations, the regulatory system for GMOs falls within what the European Commission has called “non-negotiable red lines”.

EU rules on hormones, chlorinated poultry, and GMOs, have all been challenged by other countries ever since the 1990s. The EU has so far chosen to defend its rules and basically keep in place its established regulatory system. Based on historical experience, moreover, it seems that pressure from the inside of the EU is more likely to change the regulatory system than pressure from the outside.

TTIP challenges – regulatory cooperation

As noted by Ahearn (2009), the transatlantic regulatory cooperation has for a long time had to deal with a variety of key differences between the EU and the U.S approaches to regulation. Even though the EU and the U.S. systems are closer than many other regulatory systems in the world (shared set of values, similar culture, same level of development etc.), differences complicate regulatory cooperation. In fact, variation in approaches to regulation as well as differences in the institutional set-up of regulatory systems, are generally considered to be major factors explaining the limited role of regulatory harmonization in international goods and services markets (Sykes 1999).

Political and administrative differences

The different political and administrative systems of the EU and the U.S. have implications for the decision-making process as well as for the capacity for implementation and enforcement of regulations and standards (Ahearn 2009; Vogel and Swinnen 2011; Veggeland and Evensen 2015). The European Commission has ample authority to propose new legislation and to coordinate cooperation on transatlantic regulatory issues. However, enforcement is usually left to member states, which may result in different levels of enforcement and different treatment of European and U.S. companies. The U.S. therefore occasionally raises doubts about the administrative standard and enforcement capacities of some of the EU member states. Such doubts could again create unwillingness for the U.S. to, e.g., accept conformity assessments being performed by some EU member states. This problem enters into the TTIP discussion on the EU demand that the U.S. should treat the EU as one regulatory entity and not on a country-to-country basis. On the other side, U.S. regulatory agencies generally enjoy a fair amount of independence on policy and implementation matters while at the same time the U.S. government lacks a clear-cut institutional mechanism to coordinate cooperative regulatory efforts. A great deal of responsibilities and authority are moreover delegated from the Federal to the state level. Thus, a number of political and administrative differences do not only create problems for reaching mutually agreed solutions to regulatory problems, but also create problems for maintaining regulatory cooperation agreements operative (Elvestad

and Veggeland 2004; Elvestad and Veggeland 2005; Nicolaodis and Shaffer 2005; Veggeland 2006; Ahearn 2009; Vogel and Swinnen 2011).

Political and administrative differences thus raise the question of how to achieve and maintain trust and confidence in each other regulatory systems. Dialogue, information- and data-sharing (e.g. of clinical trials), exchange of personnel, and exchange of best practises are all methods that the EU and U.S. seek to apply in the context of TTIP. The question is how they will incorporate such trust-building efforts into a binding agreement, while at the same time establishing an operative agreement, which in line with stated goals, is supposed to effectively facilitate trade.

Different approaches to regulation and risk management

The U.S. regulatory approach is characterized by broad authority being granted to the regulatory agencies to implement laws through regulations (Ahearn 2009). This decentralized model has also contributed to the discussion on the danger of regulatory agencies being “captured” by special interests. The danger of regulatory capture is also highlighted by the “bottom-up” model of the U.S. where considerable public and stakeholder input is ensured throughout the regulatory process. The requirements of the U.S. Administrative Procedures Act (APA), the Freedom of Information Act, and the Government in the Sunshine Act permit public scrutiny of regulatory activity and thus also secure a transparent regulatory process. However, this regulatory “openness” also opens up for influence by special and concentrated interests. The U.S. system may arguably allow for business and other lobbyists to play a prominent role in the regulatory process, including initiating new areas for regulation. The EU’s regulatory “top-down” approach is characterized by less stakeholder involvement and more political involvement through the participation of member state officials and European Parliament in the decision-shaping and decision-making process. The regulatory system, which is administered by the European Commission, appears as more centralized than the U.S. system. In the EU system preparing new regulations is made in cooperation between Commission officials and national experts, and regulatory decisions are either made by the political bodies of the EU (Council, European Parliament) or by the European

Commission as part of its delegated authority. A TTIP Agreement thus has to balance two quite different regulatory approaches found in the EU and the U.S. respectively.

How to deal with scientific uncertainty: the precautionary principle

The EU interpretation and understanding of the precautionary principle was first set out in a European Commission communication adopted in February 2000 (European Commission 2000; Veggeland 2002a, 2002b). In the process leading up to the signing of the Lisbon treaty in 2007, the precautionary principle was included in Article 191 of the Treaty on the Functioning of the European Union (TFEU):

2. Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.

In this context, harmonisation measures answering environmental protection requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a procedure of inspection by the Union.

The EU's regulatory framework for chemicals (Regulation (EC) N 1907/EC - known as REACH) is also based on the precautionary principle. The principle is moreover part of the General Food Law (Regulation (EC) N 178/2002)), both as a separate provision (article 7) and as part of article 6 on risk analysis:

Article 6: Risk analysis

(...) Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5.

Article 7: Precautionary principle

1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk

management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

The principle opens up for preventing measures (and thus also trade-restricting measures) to be implemented in situations where there is the possibility that a given policy or action might cause harm to the public or the environment and if there is still no scientific consensus on the issue. The EU states that the precautionary principle may only be invoked in the event of a potential risk and that it can never justify arbitrary decisions. However, scientific consensus, potential risks, and arbitrary decisions are all issues open for different interpretations – thus opening up for controversies when precautionary measures affect major trading partners such as the U.S. Also, the fact that the precautionary principle is included as a legal principle on which risk management decision in the EU are made, can complicate (as in fact was the case in, e.g., the hormones dispute) regulatory cooperation between the EU and the U.S. This is particularly in areas, such as food policy, where the two parties have different regulatory approaches and different views on scientific evidence and what are considered legitimate factors to take into account in a risk analysis (Veggeland 2001; Petersmann and Pollack 2003; Josling and Tangemann 2015).

The precautionary principle is not explicitly mentioned in available TTIP texts and proposals, but is nevertheless implicitly affected by some of the proposals, e.g. the U.S. proposal on Science and Risk to the SPS Chapter. The precautionary principle is part of EU law and thus also part of the EU regulatory (and risk analysis) framework, which forms the basis for both environmental and food safety regulation in the EU. The EU is also a signatory to the Cartagena Protocol on Biosafety, which sets out the first international legal framework for the cross-border movement of GMOs on the basis of the precautionary principle. The U.S. has not adopted the precautionary approach as a legal principle and is not part to the Cartagena Protocol. Thus, there is a possible mismatch between the risk-based approaches of the EU and U.S. regulatory regimes – a mismatch caused partly by potentially different thresholds and criteria for implementing precautionary measures. One study has concluded that in the context of TTIP, the differences between the EU and the U.S. may challenge the position of the precautionary principle in EU's regulatory regime (Stoll et al. 2015; Stoll et al. 2016). Another study argued a few years back that "(...) differences in relative precaution depend more on the context of the particular risk than on broad differences in national regulatory regimes" (Wiener and Rogers 2002: 317). In any case, exactly how the

precautionary principle can be applied in different contexts may be put under pressure by TTIP.

Values, public preferences and risk

As already noted in the discussion on the precautionary principle, differences in the U.S. and the EU regulatory approaches also include differences in the risk analysis frameworks, in particular regarding the basis for risk management decisions. For example, in the case of GMOs, the U.S. system is science-based and prefers to regulate once significant problems have been identified (Ahearn 2009). In the EU, the public tends to favour a more cautious approach, i.e. a preference for action before a problem has occurred. This more cautious approach was triggered by the food safety scandals of the 1990s thus pushing EU to set up a stricter and more comprehensive system of food regulation. As a consequence of this development, a number of European standards have become more stringent and comprehensive than U.S. standards (Ahearn 2009). European consumers increased their interest in “naturally produced” foods and organic food, whereas many U.S. consumers tend to be more positive towards products produced by advanced forms of agricultural production (ibid.). Thus, issues such as growth hormones for beef, chlorinated cleansing of poultry, and GMO meet strong reactions and resistance from consumer groups in Europe, whereas the same issues do not seem to raise much attention in the U.S.

Regulatory cooperation under TTIP – institutional issues

A possible new institutional framework for transatlantic cooperation

TTIP aims at developing the regulatory cooperation between the EU and the US beyond the VEA, the MRA and the already established transatlantic regulatory dialogue, through broader coverage and strengthening of institutional mechanisms. The EU proposes to set up a Joint Committee comprising representatives of both Parties, a Transatlantic Regulator's Forum, comprising senior regulatory officials from the EU and the US, specialized committees and working groups under the auspices of the Joint Committee (including a SPS Committee, a TBT Committee, a Market Access committee and a working group to, among other things, examine stakeholders' requests), and a Civil Society Forum, where a wide range of civil society, business and other stakeholder groups may be represented. There is also a plan to include a dispute settlement mechanism, which seems to reflect as somewhat similar dispute settlement mechanism as that of the WTO.

The EU proposals on institutional framework and regulatory cooperation emphasize the role of stakeholders in the regulatory development, c.f. for example: *Stakeholder involvement is critical for the success of regulatory cooperation activities. All natural and legal persons need to be given the opportunity to provide input to ongoing regulatory cooperation initiatives and suggest new initiatives. Appropriate modalities will need to be established for a transparent dialogue with interested natural and legal persons, both at the Ministerial and working levels* (TTIP-EU proposal for Chapter: Regulatory Cooperation, page 10). The new element in this is that stakeholders from both the EU and the U.S. will be considered as legitimate participants. A new configuration of actors will thus be established in the regulatory process. The EU's increased emphasis on stakeholder involvement and consultation in the regulatory process is in line with its so-called "Better Regulation" agenda (Elvestad and Veggeland 2010), where the European Commission aims to provide "(...) new opportunities for stakeholder comments throughout the entire policy lifecycle, from the initial Roadmap to the final Commission proposal" (European Commission 2015a). Thus, through the launch of the "Better Regulation" agenda, the "top-down"

regulatory approach of the EU, which relies heavily on member state involvement, is actually moving closer to the U.S. “bottom-up” approach, which relies heavily on the involvement and inputs from a variation of stakeholders throughout the regulatory process (Ahearn 2009; Vogel and Swinnen 2011).

EEA Agreement and third country involvement in TTIP

It is important to stress that most of the EU’s SPS rules including the General Food Law (but excluding the phytosanitary area), are part of the EEA Agreement between the EFTA countries Norway, Iceland and Liechtenstein and the EU. Moreover, many rules related to the TBT area, which are important elements of the internal market, also apply to the EEA Agreement. Thus, the EU drafting of new regulations and standards in these areas, or revision of old ones, automatically triggers a need for the EEA countries to update the EEA Agreement and adapt to EU rules. Thus, to the extent that TTIP will change regulations and standards, these countries are directly affected. Moreover, TTIP may in effect make it even more difficult for non-EU members to participate in and influence on the EU’s regulatory work. The EEA Agreement allows Norway and the other EEA countries to participate in preparatory regulatory work under the European Commission on those issues covered by the Agreement. TTIP may potentially reduce the significance of this work – given that new legislative proposals have already been shaped and influenced at an earlier stage by EU and U.S. actors who take part in the transatlantic dialogue. The emphasis made by the EU and the U.S. on early stakeholder involvement underlines this challenge.

The EFTA countries of the EEA Agreement could therefore, potentially, end up with even less influence on EEA-relevant regulations than today. One of the big challenges for these countries is therefore to find ways to get involved in the discussions and developments taking place within the EU-U.S. regulatory dialogue. The EFTA countries share these challenges with other third-countries with open economies and clear interests in gaining access to EU and U.S. markets.

All third countries face the challenge of finding ways to avoid that TTIP will create unfavorable conditions for those not taking part in the regulatory cooperation between the EU and the U.S. Joining TTIP or negotiating separate bilateral agreements could be options to consider here. EFTA countries, which through the EEA Agreement are destined to adapt to the EU’s internal market rules, face the additional challenge of finding ways to participate in relevant decision-shaping processes

taking place in the transatlantic dialogue – processes that may have a direct impact on the EEA Agreement.

TTIP and potential impact: an assessment

So far, no available data indicate that comprehensive harmonization of regulations and standards will take place as a direct consequence of the TTIP negotiations. The European Commission has been crystal clear on its position on the regulatory area: that the EU will not change its regulatory goals, will not lower its standards, and will not be willing to lose sovereignty over regulatory decisions involving basic concerns, including decisions on appropriate levels of risks. This dedication to protect the EU's regulatory sovereignty is well illustrated by the comments made by Cecilia Malmström, Commissioner for Trade in the European Commission, in her blog post called "Negotiating TTIP" on May 2, 2016 (Malmström 2016):

It begs to be said, again and again: No EU trade agreement will ever lower our level of protection of consumers, or food safety, or of the environment. Trade agreements will not change our laws on GMOs, or how to produce safe beef, or how to protect the environment.

Any EU trade deal can only change regulation by making it stronger. We might agree with a partner that rules on the safety of medicines would be tougher than before, for example, but never weaker. No trade deal will limit our ability to make new rules to protect our citizens or environment in the future.

I am simply not in the business of lowering standards. I have a clear negotiating mandate for the negotiations given to the Commission by 28 EU governments that clearly spells out what a successful agreement has to look like, and what our non-negotiable red lines are. And as always, the end result of a negotiation would have to be cleared by those 28 Member States and the European Parliament before becoming reality.

The statement from the Trade Commissioner illustrates that immediate and comprehensive harmonization of food and health regulations and standards is not part of the EU's TTIP agenda.

However, one thing is to preserve sovereignty over regulatory decisions, another thing is to open up the market for foreign goods, produced under different regulatory regimes. Thus, equivalence assessments as well as mutual recognition may, not in principle, but in

effect, allow more U.S. products into the EU market that are produced under different standards. Equivalence and mutual recognition are two of the tools that can be used to achieve regulatory convergence by gradually removing NTBs. Thus, TTIP could have long-term effects on regulatory convergence and trade facilitation. To exemplify such a scenario: The US has more liberal policies on GMOs than the EU. If the EU and the US agree that a certain way of labelling GMO products is sufficient to safeguard consumer and health concerns, more GMO products could be authorized to enter the European market – even without changing internal EU legislation on GMOs. This illustrates the potential within TTIP for “moving” decisions from public authorities to consumers and the market. In the scenario above, GMOs become more a matter of consumers’ choice than that of the governments’ choice. This becomes a particular pertinent issue in situations of scientific uncertainty (c.f. also the precautionary principle), where it is difficult to find clear scientific evidence to underpin a prohibition of placing a certain product on the market.

As the negotiations stand in 2016, the EU-US regulatory cooperation under TTIP does not seem to have any dramatic short-term effects, at least when it comes to regulatory harmonization. However, the long-term effects are more uncertain, not least because of the institutional framework, which may be established. The two regulatory regimes of the EU and the U.S. are based on different logics and approaches – the EU “farm to fork approach” and use of precaution on the one side, and the U.S. “bottom-up” approach with extensive involvement of stakeholders in the regulatory process on the other, illustrate this. TTIP may contribute to moving more of the discussions on regulatory issues to the transatlantic dialogue thus opening up for influence from a new set of actors (including EU and U.S. business and other stakeholders) in the early stages of lawmaking (“pre-legislation” and “decision-shaping” phase).

Thus, trade facilitation and transatlantic regulatory cooperation may in the long-run change the regulatory regimes of the EU and the U.S., not least by shifting emphasis towards rule-shaping activities within the transatlantic dialogue involving a new set of actors and interests in the pre-legislation phase. More of the premises – more of the preparatory work – could then be made within the transatlantic dialogue thus reducing (not necessarily formally, but in effect) the role of intra-EU preparatory work. This represents a challenge for third countries in general, but for EEA countries in particular.

The probably biggest challenge for the TTIP cooperation, however, is political. Political will, as well as legitimacy, is needed in order to achieve success in negotiating, implementing, enforcing and maintaining comprehensive trade agreements. The slow progress and finally breakdown of the 2001 Doha Round of negotiations in the WTO illustrates the problems involved. In this context, TTIP has not been put in a good position – attracting severe criticism from civil society, NGOs, as well as from a number of politicians from different countries. In addition, with the election of a new U.S. President in November 2016 and a new U.S. administration being put in place in January 2017, the future of TTIP seems uncertain. However, if the EU and the U.S. succeed in getting the negotiations back on track the process of concluding and implementing an agreement could potentially be finished by 2020.

Moreover, even if the TTIP negotiations will not succeed, the process has contributed to the identification of new issues, which may be included in the already established framework for regulatory cooperation between the EU and the U.S. Moreover, several disputes and disagreements on regulatory issues remain unsolved. Thus, regulatory issues are expected to remain crucial to future transatlantic trade discussions also in the years to come.

Summarizing conclusions

It is important to understand the TTIP negotiations on the background of the transatlantic regulatory cooperative framework, which dates back to the 1990s. Many of the regulatory issues which are on the TTIP agenda today have in fact been part of the regulatory dialogue since the 1990s. The historical development of this dialogue shows two different trends. First, transatlantic cooperation is highly prioritized and has produced some noticeable (if not always fully successful) results in facilitating trade, such as the MRAs, the VEA and the MoU, mainly by the use of “soft” tools, such as mutual recognition, equivalence and regulatory dialogues. Second, important regulatory differences prevail and history tells us that regulatory disputes involving issues of high political salience, is hard to solve. Regulatory convergence on such controversial issues seems unlikely, but could take place conditioned by changes in the political and cultural positions and conceptions within the EU and the U.S. respectively. The EU-U.S. regulatory cooperation has so far been characterized by slow progress and small, incremental steps, more than short-term dramatic shifts in regulatory approaches. TTIP appear to continue this trend. The EU and the U.S. have different regulatory systems, and in the short-run these different systems seem to prevail. However, the TTIP may provide a new and important institutional set-up for the transatlantic regulatory cooperation, including arenas and procedures for stakeholder involvement and new dispute settlement mechanisms. Such a new institutional set-up would create challenges for third countries, not least the non-EU members of the EEA Agreement, regarding how to be informed about the activities of the transatlantic cooperation and how to influence relevant decisions. Moreover, a new and strong institutional framework could as a long-term effect put more and stronger pressure on the EU and the U.S. to adapt to each other’s regulatory approaches.

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Interviews

Monday October 10, 2016

Peter Chase, Senior Fellow, the German Marshall Fund of the United States, Brussels

Garcia Bercero, EU's Chief Negotiator for TTIP, Director, DG TRADE, Brussels

Norway's delegation to the EU, meeting with three trade officials, Norway House, Brussels

Léa Auffret, Trade Policy Officer, BEUC (the European Consumer organisation), Brussels

Tuesday October 11, 2016

U.S. delegation to the EU, meeting with three trade officials, U.S. Embassy, Brussels

Manuel Catalan-Rodriguez, Policy Officer, DG MARE, Brussels

Brian Kilgallen, Policy Officer, EU-US Trade at European Commission, DG SANTE, Brussels

Arnaud Petit, Director, Commodities and Trade, COPA-COGECA, Brussels

Appendix 1: Publicly available negotiation texts on food and health regulations per September 2016⁶

Regulatory cooperation:

[Revised EU proposal on regulatory cooperation](#) 

[Introduction to the EU's proposal on Good regulatory practices](#) 

[Benefits of regulatory cooperation](#) 

Good Regulatory Practices (GRPs):

[New EU proposal on Good regulatory practices](#) 

[Introduction to the EU's proposal on Good regulatory practices](#) 

Technical Barriers to Trade (TBTs)

[Technical Barriers to Trade \(TBTs\) in TTIP](#) 

Food Safety and Animal and Plant Health (SPS)

[SPS in TTIP](#) 

EU proposal to include an article on [Anti-Microbial Resistance within the SPS Chapter of TTIP](#) 

Medical Devices

⁶ TTIP Draft chapter proposals, which included both EU and U.S. proposals, were made available by Greenpeace in May 2016. The proposals included the following topics: National Treatment and Market Access for Goods, Agriculture, Cross-Border Trade in Services, Electronic Communications, Government Procurement, Annex Government Procurement, Customs and Trade and Facilitation, EU – US revised tariff offers, Regulatory Cooperation, Technical Barriers to Trade, Sanitary and Phytosanitary Measures, Competition, Small and Medium-sized Enterprise, State-owned Enterprise, Dispute Settlement, and Tactical State of Play.

EU position paper on [Medical devices in TTIP](#) 

[EU's proposal for an annex on medical devices in TTIP](#)  NEW

Pesticides

Only factsheets so far: [Factsheet on Pesticides](#) 

Pharmaceuticals

EU position paper on [Pharmaceuticals in TTIP](#) 


EU position paper on [Generic Medicines in TTIP](#) 

[EU Proposal for an Annex on Medicinal Products](#) 

Intellectual Property (IP) and Geographical Indications (GIs)

EU position paper on [Intellectual Property in TTIP](#) 

EU textual proposal on [IPR border measures](#) 

EU textual proposal on [Provisions on international agreements relating to Intellectual Property in TTIP](#) 

[EU concept paper on Geographical indications \(GI's\)](#) 

[EU proposal - text outline for GI's](#) 

Annexes

[I: List of foodstuffs](#) 

[II: List of spirit names](#) 

Institutional, General and Final Provisions

[EU Proposal for Institutional, General and Final Provisions](#)  NEW

Appendix 2: Definitions – the WTO’s TBT Agreement’s definitions of technical regulations and standards and the WTO’s SPS Agreement’s definition of a SPS measure (Sanitary or phytosanitary measure)

TBT Agreement

Annex 1: Terms and their Definitions for the Purpose of this Agreement

1. Technical regulation

Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

2. Standard

Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

SPS Agreement

Annex A definitions

1. Sanitary or phytosanitary measure – Any measure applied:

(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or

(d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.



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About the author:

Frode Veggeland holds a PhD in Political Science and is Professor at the University of Oslo, Department of health management and health economics, and Senior Researcher at NIBIO. Among his specialized fields of competence are studies on international organizations (WTO, EU, WHO/FAO), public administration, regulatory cooperation, and food, health and trade policies.

NUPI

Norwegian Institute of International Affairs
C.J. Hambros plass 2D
PO Box 8159 Dep. NO-0033 Oslo, Norway
www.nupi.no | info@nupi.no