



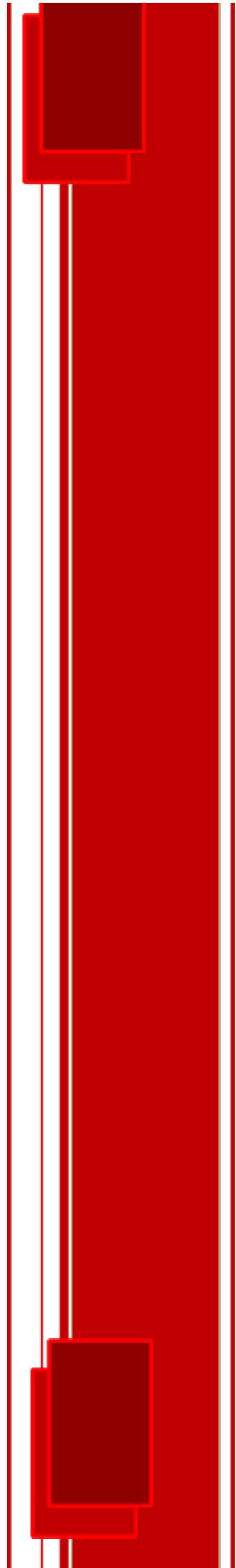
THE LONDON SCHOOL
OF ECONOMICS AND
POLITICAL SCIENCE ■

THE TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP: INTERNATIONAL TRADE LAW, HEALTH SYSTEMS AND PUBLIC HEALTH

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1.0 EXECUTIVE SUMMARY

1.1 Study Overview

Free trade agreements (FTAs) have the declared aim of seeking to increase global trade and promote economic growth. Historically, economic growth has led to improved population health. Yet this link is now weakening, and attention is being focussed on assessing the effect of FTAs on health and the ability of government to mitigate against negative impact. Within this context, this study presents an assessment of the health impact of the proposed FTA between the United States and the European Union.

The proposed Transatlantic Trade and Investment Partnership (TTIP) between the US and the EU constitutes the largest ever FTA of its kind.

Although the TTIP mandate has recently been made public, access to negotiating texts remains limited and it is apparent that much detail on TTIP is still to be agreed. With this in mind the aims of this rapid evidence assessment are:

- To summarise and critically evaluate available evidence on the health related risks and benefits of TTIP;
- To make an assessment as to the overall health impact that TTIP may be expected to have; and
- To provide guidelines for the European public health community about priorities that they could be focussing on, as they respond to the TTIP negotiating process.

The study is based upon a structured and systematic rapid evidence assessment and a targeted stakeholder engagement process, commissioned to run over an eight-week time period during August and September 2014.

1.2 TTIP in Context

TTIP forms part of a widening international trade agenda that has moved from tariff reduction to trade liberalisation, investment protection and regulatory reform. In terms of scale, scope and remit the TTIP represents a significant new development in European trade policy and regulatory reform.

There is currently a mosaic of pre-existing Bilateral Investment Treaties (BITs) between individual Member States and the US, each of which varies in form and content. Nine current Member States including Poland, the Czech Republic and Croatia have a current BIT with the United States. The TTIP is designed to replace these with a single FTA covering all 28 Member States of the European Union.

There are links between the proposed TTIP and post-war international trade liberalisation that saw the establishment of the World Trade Organisation (WTO), the subsequent development of the General Agreement on Tariffs and Trade (GATT) and

the General Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

The reform programme initially focussed on tariff reductions and is commonly recognised as having underpinned a period of rapid global economic growth. This agenda has now been expanded to include consideration of a range of non-tariff related regulatory issues. Failure of the 2001 Doha round of the GATT process to reach universal common agreement on non-tariff issues then heralded a tactical realignment with the development of a parallel reform track based upon interlocking multilateral level trade agreements.

The TTIP negotiations were initiated at the G8 meeting in Northern Ireland in 2013. For the US, they formed a further strategic FTA to the North Atlantic Free Trade Agreement (NAFTA) and the Trans Pacific Partnership (TPP). The TTIP also shares similar policy goals and negotiating structure to the EU-Canada Comprehensive Economic and Trade Agreement (CETA) that was instigated in May 2009. TTIP and CETA represent the first FTAs to be negotiated following the signing of the Lisbon Treaty in December 2009. This treaty had extended the EU's powers within the area of foreign and domestic investment (FDI) and introduced the requirement for the European Parliament to ratify FTAs.

Evidence suggests that both the US and the EU are seeking regulatory reform from TTIP, and are additionally viewing the TTIP as a vehicle for post 2008 recession recovery.

TTIP is considered by proponents and opponents to be fundamentally different to other FTAs on the basis that:

- The majority of projected gains are to accrue from regulatory as opposed to tariff reform;
- US and EU trade representatives describe it as being a blueprint for future FTAs; and
- It is described as being a 'living agreement' that will see structures established to oversee on-going regulatory reform subsequent to initial ratification.

For proponents, these three features will help to deliver growth alongside improved regulation, whilst critics argue that they could lead to a reduction in regulatory standards as well as restricting the ability of the state to regulate in the public interest.

1.3 Overall Impact of TTIP

Proponents estimate that benefits in excess of €200bn could be realised within two decades of the TTIP agreement being signed, the majority of which would come from non-tariff based reform. Critics have challenged the methods and assumptions used to develop these estimates, and evidence from other FTAs suggests that economic impact is difficult to measure and attribute. Consequently, projections of net economic benefit should be treated with caution.

Studies undertaken by the European Commission suggest overall economic gains accruing from TTIP would equate to a one off increase in European GDP in the range of 0.3% to 1.3%, with a similar level of gain for the United States' economy.

There is an established link between GDP growth and improved population health, however this needs to be set against recent assessments which posit a weakening of the effect size, most particularly for More Developed Countries (MDCs). The manner in which additional wealth is utilised in MDCs is also of note. Research suggests that it is key in determining whether it will have a positive or negative effect on living standards and health status.

Critics have also challenged the reliability of the assumptions used to underpin the economic modelling and contend that the social costs of regulatory change and loss of state revenue have not been fully accounted for.

Outside of Europe and the US, studies examining the potential impact of TTIP contend trade between Less Developed Countries (LDC) and the EU to be most at risk from TTIP. However, the overall impact looks to be limited as key sectors for LDCs such as textiles are unlikely to be impacted.

1.4 Thematic Impact of TTIP

The health impact of TTIP will emanate from both goods and services - particularly food, pharmaceuticals and the delivery of health services. Few overall specific health benefits were identified, while the scale and impact of disbenefits will be dependent on a highly complex interplay of factors.

TTIP is divided into a number of chapters, the following of which have been identified as being most likely to have aspects that could impact upon health.

1.4.1 Trade in Goods

There appears to be limited health related benefits that could accrue from the TTIP in relation to trade in goods, while the largest single health risk will arise from tariff reductions leading to increased consumption of unhealthy foods.

Proposed reductions in tariffs on processed foods have been projected to generate one of the largest percentage increases in imports of goods by sector. If existing tariffs were to be significantly reduced or eliminated and current restrictions lifted, then evidence suggests imports into the EU of US agri-food produce could double by 2025, albeit from a low baseline. Whilst this may have a positive economic impact on consumers by

reducing some food costs, evidence suggests that this could be undermined by the negative health impact of increasing the availability and reducing the price of unhealthy foods, which are particularly price sensitive.

Secondly, TTIP could lead to increased imports of Genetically Modified (GM) crops and produce, which are currently subject to restrictions, as well as hormone treated beef, the import of which is currently illegal within the European Union. EU negotiators continue to state that the regulatory position of these goods will not change as a result of TTIP, even though the evidence base on their health impact remains highly contested.

1.4.2 **Technical Barriers to Trade (TBT)**

Health related TBTs primarily relate to pharmaceuticals and agri-food. TBTs could positively impact on health if pharmaceutical regulatory efficiencies were realised, yet such benefits might be offset by concomitant increases in pharmaceutical costs resulting from other provisions within the TBT chapter. No estimates of the overall impact were identified during the evidence review.

The importance of the pharmaceutical industry to the European and US economies is well established, and a particular focus for the European Commission is to address the decline in market share of European companies during the first decades of the new millennium.

Within the pharmaceuticals sector there is a broad consensus that the commitment to regulatory convergence within TTIP could result in significant efficiencies in relation to the authorisation of clinical trials data. The potential for increased cooperation between the European Medicines Agency (EMA) and the Federal Drugs Administration (FDA) could result in reduced duplication of processes and improved research cooperation. This could enable medicines getting to market more quickly. However, there are also concerns that TBT provisions within TTIP could impact on transparency, with some groups arguing that industry would be more able to limit the sharing of relevant data, additionally affecting member state pricing and reimbursement policies and practices.

The determination of pharmaceutical prices remains a highly complex process. Consequently, whilst two measures have been identified which could put an upward pressure on prices and one that could apply a downward pressure, no estimates of their likely overall impact were identified during the review.

Agri-food could be impacted primarily in relation to food labelling, where the TBT chapter of TTIP could provide an additional platform for industry to challenge regulations. However, evidence of WHO TBT provisions being used to challenge the right to regulate demonstrate that the ability to challenge public health related food labelling will remain, whatever provisions are finally agreed in TTIP.

1.4.3 **Sanitary and Phytosanitary Issues (SPS)**

Short- to medium-term health-related risks associated with the SPS chapter of TTIP appear to be limited. Whilst there are different food safety systems operating in the US and the EU, the evidence of there being differential health impact is inconclusive. Although increased cross-border trade could increase health risks, it is difficult to

estimate overall potential impact. Longer term rationalisation of SPS provisions offer both opportunities and risks.

Evidence from other FTAs suggests that increased cross border trade in products with different regulatory systems and standards could increase the risk of outbreaks of diseases such as Hepatitis A, although comparability is limited.

TTIP is unlikely to see an increase in imports of goods that do not meet current EU standards, such as hormone treated beef, as this is a long standing issue which is unlikely to be resolved at this juncture. Even if restrictions were lifted, the evidence on potential harm is inconclusive and remains contested.

There have been repeated assurances from negotiators that TTIP will not require either party to lower its regulatory standards. The focus appears to be on mutual recognition of existing standards. No evidence was identified from other trade agreements of there having been a levelling up of standards.

1.4.4 **Trade in Services**

The main health focus within the Trade in Services chapter relates to public procurement and the exclusion of health services from TTIP. The impact of privatisation on efficiency, quality and employment terms and conditions is well evidenced. Consequently, as the boundaries between 'social' and 'commercial' services continue to blur, the precise wording of any 'hard' or 'soft' exclusion will be of importance. The greatest consequence would be to those Member States that choose not to explicitly exclude their health services from TTIP.

The following two areas of risk have been identified from the evidence review:

- That TTIP will require publicly run health services to be opened up to competition from private sector healthcare providers; and
- That a 'ratchet clause' and negative listing in TTIP would preclude the possibility of privatised public services being returned to state operation.

Underpinning the concern about health services is the argument that health, alongside other public services, are not suitable for traditional market competition and as such should be fully or partially excluded from the trade in services provisions within TTIP. Those studies that have provided evidential support for such assertions cite issues such as inefficiencies arising from the contracting process for outsourced delivery of care.

EU negotiators have made a clear commitment that there will be an exemption for public services from TTIP, and that this exclusion will include publically run health services. However, it appears that TTIP will include a soft exclusion or 'exemption' rather than a hard exclusion or 'carve out'.

Individual Member States will have to make an explicit decision whether to include or exclude their national health services. At Member State, level the UK is one country where evidence suggests that the government may not seek to exclude all of its health services.

The second associated public procurement issue relates to renationalisation and whether the public procurement provisions, when linked to investor protection, could 'lock in' current or future privatisation through the use of a 'ratchet clause'. The EU negotiating team have issued further assurances that the ability of Government to determine its own policy would be protected. However, much will rely on the position with regard to ISDS (see section below), and the final decision of Member States with regard to seeking the exclusion of health services from TTIP.

Finally, TTIP could potentially impact on health were there to be increased mutual recognition of qualifications. However the final decision as to whether or not to accept overseas qualifications will rest with individual Member States. It should also be noted that TTIP does not include any provisions relating to freedom of movement.

1.4.5 **Investor Protection**

The single most contested aspect of the TTIP negotiations relates to the proposed inclusion of an Investor to State Dispute Resolution (ISDS) arbitration system. Evidence of the current operation of ISDS provides only limited substantiation to the assertion that it constitutes a significant new area of risk to public health regulation. At the same time, the ability to legally challenge public health policy will remain in other international law even if a final decision is taken to remove or fundamentally amend the investor protection provisions in TTIP.

The challenge of ISDS is summarised as follows:

- ISDS allows claims for the expropriation of investor profits;
- ISDS can lead to 'regulatory chill' as governments may desist from undertaking regulatory reform for fear of legal action;
- ISDS takes arbitration out of national legal frameworks to third party arbitration tribunals;
- There has been a significant increase in ISDS cases over the last years;
- A small proportion of ISDS cases have related to core health service issues; and
- A number of countries are now withdrawing ISDS from existing and proposed BITs.

The counter argument is that:

- Assessment of ISDS cases to date demonstrates that more were concluded for government than business, and more have been settled prior to coming to court;
- A majority of ISDS cases to date have been taken within the EU, not the US;
- The majority of ISDS cases have been concluded in favour of national governments;
- Awards made have been significantly below the level of initial claims;
- ISDS is already present in BITs between EU Member States and the United States, yet there has not been an ISDS case between the US and the EU15 to date; and
- The ISDS provisions proposed for TTIP provide increased protection against inappropriate claims than existing ISDS provisions within BITs.

There are very few empirical studies relating to the potential impact of ISDS, but those such as the study for the Netherlands Government believe the overall risk to be overstated, with evident potential to militate against what risk there is.

The inclusion of ISDS is currently the subject of a formal Public Consultation exercise that has been instigated by the European Commission, while Member States such as Germany are now publically airing doubts about its inclusion.

It currently appears likely that ISDS will either be withdrawn from TTIP or will be subject to further revision that could include greater transparency, revision of the extra-judicial process and/or the inclusion of additional safeguards against potential misuse. Evidence suggests that the exclusion of ISDS would have a limited impact on investment levels.

1.4.6 **Intellectual Property**

Intellectual property (IP) may have a range of health related impacts, of which the pharmaceutical impact is likely to be the most important. Whilst there is currently a high level of accord between the two trading blocs, there remain some differences. If TTIP were to fully align to US provisions on IP, it may positively impact on innovation yet could also create an upward cost pressure.

Given that pharmaceutical costs represent 1.5% of European GDP, any increase in IP protection arising from TTIP might have a tangible impact on healthcare costs. The health impact of the intellectual property chapter in part relates to the issue of patent protection and regulatory data protection (RDP) for pharmaceuticals. There is close alignment between the US and EU but some differences remain. For example there is no continuity on how prior user rights are defined, how patent applications are handled or even how patentability is determined.

1.4.7 Regulatory Cooperation and Reform

As a 'living agreement', regulatory cooperation and reform is likely to be an integral ongoing aspect of the TTIP agenda. However there is insufficient evidence to make prior determination as to whether long term regulatory cooperation and alignment would have a beneficial or detrimental health impact.

The TTIP sets out an ongoing commitment to increased regulatory alignment, but at the same time asserts that it will not result in any reduction of current standards.

Given the need to generate both direct and indirect savings from the regulatory reform process, many stakeholders posit that an initial focus on achieving reform through mutual recognition and increased regulatory alignment will be superseded by one that seeks a deeper level of regulatory convergence.

The two broad approaches to risk management through regulation are the evidence-based and precautionary approaches. Commonly, the US is caricatured as adopting the former and the EU the latter. This is too simplistic and the TTIP does not out-and-out favour either approach. However, some commentators believe the commitment to "efficient and cost-effective" regulation could in practice present a significant challenge to the precautionary approach. The consequent impact of moving from a precautionary to a more evidenced-based risk approach is equally difficult to predict on the basis of current evidence.

1.4.8 Regulatory Health Policy Space

Public health regulation is now increasingly focussed on non-communicable disease issues. TTIP presents only limited additional legal scope for stakeholders to challenge the ability of government to regulate in this area.

Regulation in support of public health goals is a common feature within the US and EU, with many aspects decentralised to national, regional and municipal level. Within this context a number of commentators contend that TTIP would open aspects of public health regulation to legal challenge. In support of this, international examples have been highlighted which relate to the labelling and advertising of food, alcohol and tobacco.

An assessment of the evidence suggests the principal regulatory risk to emanate from ISDS provisions within the TTIP, with such risk being both direct and indirect. The direct and indirect risk are respectively termed:

- **Regulatory snare** – whereby a government finds itself involved in often long term and resource intensive legal process to defend itself from a claim; and
- **Regulatory chill** – whereby a government is dissuaded from initiating or continuing with a particular regulatory change for fear of a potential claim and its consequences.

The evidence review was able to evidence the 'snare' impact of claims on government, but only limited evidence of regulatory chill was identified.

Whilst some commentators believe the TTIP constitutes a risk to the future right to regulate, the evidence review has not established significant additional risk to that already presented by existing national, European and international trade law.

1.5 **TTIP Governance and Accountability**

There has only been limited stakeholder engagement in the TTIP negotiating process and limited transparency, although it appears to be a more open process than with prior FTAs. TTIP also includes a developed governance structure, reflecting the commitment to the establishment of a 'living agreement'.

Public opinion polls have been broadly supportive of TTIP, but there is increasing evidence of citizen concerns relating to particular issues such as ISDS and the potential outsourcing of health services.

There has also been a recently failed attempt to establish a Citizens Initiative, which appeared close to achieving the required one million registered EU citizens to challenge both the TTIP and CETA negotiating process.

TTIP has initially followed a common approach of FTAs in being subject to limited public scrutiny, although the EC has undertaken specific public consultation exercises on the issues of ISDS and the potential impact of TTIP on small- and medium-size enterprises (SMEs).

The negotiating mandate for TTIP has recently been declassified and civil society representatives have been given a limited advisory role on a specially established group. TTIP also envisages the establishment of an intra-regulatory governance structure, with sub-committees for chapters such as SPS as well as for broader regulatory cooperation. These are likely to be of increasing importance over time, given the unique 'living agreement' status given to the TTIP by both negotiating teams.

1.6 **Study Recommendations**

There remains a strong commitment to concluding the TTIP negotiations, and as such stakeholder groups should take a proactive, systematic, engaged and evidenced based approach that is focussed on supporting a positive growth agenda, protecting the right to regulate and mitigating areas of potential risk.

The suggested response of civil society organisations should involve focus, engagement and challenge and should recognise that TTIP forms just one element of a wider platform of international trade law, which is increasingly focussed on non-tariff issues.

- **Focus** - Should be put on those chapters of TTIP that are of the greatest importance to health such SPS, TBT, IP and Services, as well as to broader regulatory themes such as the precautionary principle.
- **Engagement** - There is a need for the public health community to continue to seek to positively engage in the TTIP development process, so as to ensure the common understanding of regulatory boundaries.



- **Challenge** - Our assessment has identified the absence of systematic assessment of the health impact of each of the relevant chapters within TTIP. Increased use of economic impact assessment tools and techniques could help to address this issue and provide a more robust evidence base.

2.0 Study Overview

The EU and the US constitute the two largest trading entities in the world. As such, current plans to establish TTIP as an FTA is of importance not only to their own citizens, but also to the global community as a whole.

2.1 Study Aims and Objectives

The research study provides an assessment of major trends in free trade policy. It traces the development of bi-lateral agreements and the expansion of the remits of FTAs to include policies on non-tariff and investment protection and arbitration issues. There is also an assessment of broader global trade governance matters as they relate to health policy.

The study aims and objectives were as follows:

- Understanding the historical evolution of free trade agreements and their potential impact upon health status and healthcare policies and practices;
- Critically examining the aims and objectives of TTIP;
- Categorising and quantifying the major health sector and public health impacts of FTAs to date;
- Assessing, on the basis of the information available, the potential health and healthcare policy and practice benefits from the implementation of a finalised TTIP agreement;
- Estimating the overall value of such benefits that could result;
- Identifying the areas of risk within the health domain that might be associated with the implementation of a finalised TTIP agreement;
- Giving particular consideration to the interface between health policy and public health, particularly in relation to foods as well as non-alcoholic sugar-sweetened beverages, alcohol and tobacco; and
- In the light of the above, developing a public health focused strategic response framework for EPHA and its members.

2.2 Research Programme

The research study was commissioned to be undertaken over a ten-week period, utilising secondary evidence review, stakeholder engagement¹ and impact assessment approaches.

The evidence review has been web based using standard and academic search engines, with a selection process that has sought to identify relevant, rational and evidence-based academic journal articles as well as grey literature representing the views of as broad a range of stakeholders as possible.

¹ Stakeholder formally interviewed were Robert Stumberg, Professor of Law and Director Harrison Institute for Public Law | Georgetown Law, Jaydee Hanson Senior Policy Analyst Center for Food Safety, and Benn McGrady, PhD Project Director, Initiative on Trade, Investment and Health O'Neill Institute for National and Global Health Law. In addition the Research Director has attended a number of conferences on TTIP in the Brussels and Washington and has presented on the study at two conferences including the EPHA Annual Conference in November 2014.



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The rapid evidence assessment has been drawn together into an EPHA Conference presentation in September 2014 and a final report in December 2014.

3.0 International Trade and Health in Context

A widening of the agenda to trade liberalisation investment protection and regulatory reform has followed a successful programme of international tariff reductions. As attempts to introduce such reforms at a global level have faltered, countries have sought to advance these goals through a series of larger bi-lateral and multilateral investment treaties. TTIP would be one of the largest such tariff, investment and regulatory treaties to be agreed.

3.1 Free Trade Law

The classical case for free trade was first forwarded by Adam Smith, in a riposte to the mercantilism of the day. At its heart is the idea that a wider market allows for deeper specialisation and division of labour. David Ricardo further developed the argument, stating that international trade is not driven by absolute costs of production, but by opportunity costs. A closer look at the efficiency gains of free trade highlights the intensification of competition over the realisation of economies of scale. On this basis free trade must be considered an essential element in spurring innovation and growth. This in turn helps ground the case for agreements such as TTIP, where a broader and deeper market leads to productivity gains and, indirectly, increased welfare for all.

The underlying argument put forward by Ricardo has been further developed by those who believe free trade to be a necessary but not in itself a sufficient precondition for prosperity². The argument is forwarded that in order to reap maximum gains, free trade must be accompanied by provisions such as property rights and the rule of law, as well as through the provision of stable macroeconomic policies. As will be discussed later, TTIP is deemed to be a more expansive FTA because it is focussed on these accompanying elements of market reform.

This current debate on the value of TTIP can be linked to an on-going and broader ideological debate between the free market and social market models. The social market model takes a much more active stance on regulatory measures. According to the proponents of TTIP, the models of both the EU and US economies must look to converge for efficiency gains to be realised³. The treaty's detractors hold that such convergence will err towards the free market in its framing and will thus weaken regulation⁴.

There is a parallel discussion that focuses on how the economy and economic development impacts on health. The term 'health policy space' is often used to describe the juncture where economic theory and practice meets public health policy and practice. This returns as a continuing theme in FTAs with the healthcare sector often categorised in a manner so as to exclude it from the full provisions of a FTA, on the basis that health is unique in that it focuses on underpinning a fundamental right and/or that market failure is both more likely and more problematic than other areas of economic activity.

² See, for example, chapter 5 of JS Mill's 'On Liberty' (1859).

³ http://trade.ec.europa.eu/doclib/docs/2013/september/tradoc_151787.pdf

⁴ <http://www.portugal.gov.pt/media/1283558/Prospects%20for%20regulatory%20convergence%20under%20TTIP%20%28English%29.pdf>

3.2 Public Health Law

On the grounds of being able to protect public health, the legal basis for the state's intervention in the market is historically well established. With roots in common law there has been a clear and long-standing link between infection control and regulation. Understanding this historical context helps to make sense of the movement from regulation of infection control to that of non-communicable diseases.

Current developments in international public health law can be traced back to a European movement to bring together infection control practice with the right to health as part of the post Second World War settlement⁵. Writers such as Taylor and Bettcher assert that international cooperation in public health matters should be viewed as being "a fluid process, ranging from non-binding instruments, such as recommendations, guidelines, resolutions and declarations to binding ones such as treaties"⁶.

The World Health Organisation (WHO) Constitution, Article 55 of the United Nations (UN) Charter and the International Covenant on Economic, Social and Cultural Rights (ICESCR) provide a basis for action. It has seen the WHO move from developing non-binding instruments to instruments of a more binding nature such as the Framework Convention on Tobacco Control (FCTC).

The principles of international trade, as recently set down by bodies such as the World Trade Organisation (WTO), are increasingly relevant to public health law. Whilst FTAs such as the North Atlantic Free Trade Agreement (NAFTA) and the Canada Europe Trade Agreement (CETA) allude to the idea of sustainability within their preamble or objectives, there is limited specific mention of the promotion of health or societal well-being. As a consequence some health policy issues such as access to medicines or tobacco control are challenged by the terms of trade law.

Writers such as Wallerstein talk about how globalisation has modified the manner in which power is distributed amongst states and how regulatory power is exercised⁷. This constitutes a paradigm shift, although the extent to which citizens are fully aware of how the potential shift of powers away from nation states or from them as citizens is less certain.

Equally when considered at an aggregate level, as writers such as Valdi has done, then it is possible to see how trade and health goals can align or even reinforce each other. However when one examines the issue at a more granular level, it is apparent that not only are there significant areas of potential conflict, but that such conflict could in fact generate fundamental discord. When asked about the ability of an FTA such as TTIP to be mutually compatible in supporting the aims of trade and public health Professor Robert Stumberg at Georgetown University commented that, whilst "it may look like a 'win-win' from an orbit of 60,000 feet, this is far less the case when viewed from 60 feet"⁸.

⁵ Vadi P 26-27

⁶ Taylor, A and Bettcher, D (2002) in Valdi p. 33

⁷ I. Quoted in Vadi (2013) page 47

⁸ Interview with Professor Robert Stumberg

The Era of Multilateralism: from GATT to the WTO

Multilateral trade treaties came into prominence in the post-war period with their roots in the experience of widespread protectionism during the interwar years. The Wall Street crash led to the Smoot-Hawley Act of 1930, which raised US import tariffs by an average of 20%. According to Madsen, reciprocal tariff walls were raised and non-tariff barriers imposed, so that world trade declined by about a third in the period 1929-1932⁹. As Anderson and Norheim find, by the onset of the Second World War, world trade had fallen to 70% of its 1928 level¹⁰. It is widely acknowledged that protectionism had proved to be a major factor in prolonging and deepening the Great Depression.

The post-war period ushered in a set of world governance institutions based on the experience of the interwar years. In 1947, the General Agreement on Tariffs and Trade (GATT) was signed by 23 countries to address the danger of protectionism and promote global prosperity. GATT introduced a forum for on-going negotiations for promoting free trade based on the most favoured nation (MFN) and non-discrimination principles¹¹. It also enacted a ratchet mechanism to prevent any return into protectionism once tariff rates have been agreed on (apart from built-in 'safeguard' clauses). Each round of talks brought down tariffs. According to the Economist, GATT has reduced tariffs from an average of 40% to 4% in participatory countries, and has accompanied a 16-fold rise in global trade¹².

GATT has always been central to Europe-US trade relations, and a brief history puts the size of TTIP into perspective. The Kennedy round, which saw highly significant tariff reductions (a 35% cut, on average), was a response to the establishment of the common European market in 1958. These cuts were across the board, with exemptions made only for sensitive sectors. The subsequent Tokyo round began the trend of addressing non-tariff barriers to trade, as well as cutting tariffs by a third again. The Uruguay round in 1986 introduced the WTO as a platform for negotiating, administering and implementing FTAs.

The Uruguay round was also important as it also saw the first steps on extending the principle of non-discrimination to new areas of international commerce: the General Agreement in the Trade in Services (GATS), the Agreements on Technical Barriers to Trade (TBT), Sanitary and Phytosanitary Measures (SPS), Government Procurement (AGP), and Trade-Related Aspects of Intellectual Property Rights (TRIPS) and of Investment Measures (TRIMS). These advancements of liberalisation into new sectors set the tone for the next two decades. NAFTA (1994) was the first FTA to bring the spirit of the Uruguay round into considerable force. The failure of the Doha round marked the decline of multilateralism and the rise of regionalism.

⁹ Madsen, Jakob B. "Trade barriers and the collapse of world trade during the Great Depression." *Southern Economic Journal* (2001): 848-868.

¹⁰ Anderson, K. and H. Norheim (1993), 'Is World Trade Becoming More Regionalized?', *Review of International Economics*, Blackwell Publishing, vol. 1(2), pages 91-109, June.

¹¹ The MFN (most favoured nation) clause in automatically extends the lowest tariffs negotiated with one country to all other countries. However, Article 24 of GATT permits countries to make an exception in the case of FTAs and customs unions.

An example of non-discrimination is the National Treatment clause, which commits governments to treating domestic and foreign products with the same regulatory standards.

¹² "Survey of world trade: Time for another round", *The Economist*, Oct 1st 1998

Dates	Trade Agreement Event	Developments
1947	GATT established	23 member countries. Tariff reduction by about 20 %.
1949-61	Four GATT rounds	18 new member countries. Tariff reduction by around 3% in each round.
1958	European Common Market established	Near-comprehensive tariff eliminations in the six member countries.
1964-67	GATT Kennedy round	Tariff reduction by about 35 %.
1973-79	GATT Tokyo round	Tariff reduction by about 33 %. Introduction of non-tariff measures.
1986-94	GATT Uruguay round	WTO, GATS, TRIMS, and TRIPS established.
1994	NAFTA established	Regional FTA era. Near-comprehensive tariff eliminations. Entrenchment of Uruguay-round agenda.
2001-	GATT Doha round (stalled)	
2004	AUSFTA, US-Chile FTA established	
2011-12	KOREU, KORUS established	
2014	CETA, TTIP, TTP, TISA in various stages of completion	

Figure 1 Timeline of Significant FTAs

3.4 **General Agreement in the Trade in Services (GATS) and the Trade in Services Agreement (TISA)**

Perhaps because of the sensitive nature of liberalising trade in services, GATS was negotiated outside of the rigorous GATT framework. The agreement was plurilateral (voluntary) for GATT members and, significantly, did not require reciprocity in liberalisation; it gave a large degree of autonomy to signatory states as to the level of liberalisation to which they could commit. GATS precluded any significant standardised agreements on essential matters such as repatriation of capital and tax treatment. According to Thornberg and Frances¹³, this meant that countries only liberalised service imports in sectors in which they had a comparative advantage, retaining protection in their relatively inefficient sectors, thereby rendering the whole exercise redundant from the point of view of free trade.

Health is one of the sectors with the fewest signatories in GATS. This is because, as many commentators emphasise¹⁴, liberalisation in a health market may significantly distort the ability to provide services to all income groups. For example, the liberalisation of health insurance may result in insurers cutting services to the poorest. Similarly, liberalising hospitals may attract the most qualified staff to the private sector, leaving the basic public system with less well qualified staff, in what the WTO

¹³ Thornberg, Christopher F., and Frances L. Edwards. "Failure of Trade Liberalization: A Study of the GATS Negotiation." *J. Int'l Bus. & L.* 10 (2011): 325., <http://scholarlycommons.law.hofstra.edu/cgi/viewcontent.cgi?article=1172&context=jibl>

¹⁴ see, for example, Mackintosh et al. (2005), 'Commercialization of health care: global and local dynamics and policy responses'

Secretariat termed “cream skimming”¹⁵. In the international context, trade in services may lead to ‘brain drain’ and severe shortages of professionals in developing countries.

TISA is currently in negotiation and can be considered “GATS plus”. One commentator in the evidence review claims that although it is taking place outside of the WTO framework, the intention being to bring TISA in line with GATS at a later date¹⁶. Of particular relevance to this study, other commentators in the literature frame TISA as a broader and shallower agreement on trade in services designed to accompany TTIP’s (more profound) services chapter¹⁷.

TISA is being negotiated by the so-called “Really Good Friends of Services” group, 23 liberalised countries, which broadly span the TTIP and TPP membership. The prospective agreement is typical of the new wave of regional FTAs in that it is a negative-list treaty with a standstill and ratchet clauses to lock in current and future privatisations. It is likely that TISA will be a reciprocal treaty, to avoid the failure of GATS.

Talks are in secret and, according to a paper leaked on Wikileaks; the TISA draft is classified until five years after the TISA is implemented¹⁸. The paper shows that the focus so far has been on the potential impacts on financial services, but other stakeholder groups are already expressing fears over its effects on public health provision¹⁹. According to one such group, TISA may lead to irreversible privatisation; restrictions on health and safety regulations, as well as environmental and consumer protection regulations; restrictions on the licencing and accreditation of public services²⁰.

3.5 Further International Trade Treaties

Further treaties have been agreed in relation to Technical Barriers to Trade (TBT), Sanitary and Phytosanitary Measures (SPS), Government Procurement (AGP), and Trade-Related Aspects of Intellectual Property Rights (TRIPS) and of Investment Measures (TRIMS). Any country wishing access to the trade treaties encompassed by WTO membership is obliged to adhere to these accompanying treaties (except AGP).

UNCTAD, the United Nations Conference on Trade and Development, states that TRIMS are rules that specify WTO provisions on “national treatment”: they ban any discrimination against foreign products. In practice, although it is contested that TRIMS has been used to impose certain “performance requirements”²¹ on foreign investment.

¹⁵ ‘Health and Social Services-Background Note by the Secretariat’, Council for Trade in Services, WTO [S/C/W50]- 18/09/98.

¹⁶ https://www.policyalternatives.ca/sites/default/files/uploads/publications/National%20Office/2014/04/TISA_Versus_Public_Services.pdf

¹⁷ http://mddb.apec.org/Documents/2013/SOM/SOM-ABAC-PECC-DIA/13_som-abac-pecc_dia_002.pdf, and <http://www10.iadb.org/intal/intalcdi/PE/2013/12580.pdf>

¹⁸ <https://wikileaks.org/tisa-financial/press.html>

¹⁹ <https://wikileaks.org/tisa-financial/Analysis-of-secret-tisa-financial-annex.pdf>

²⁰ <http://ourworldisnotforsale.org/en/signon/international-civil-society-sends-letter-governments-opposing-proposed-trade-services-agreeme>

²¹ See p.2 of the 2003 UNCTAD report on Performance Requirements for a detailed explanation http://unctad.org/en/docs/iteiia20037_en.pdf

Evidence in the literature review found that while this is ostensibly to fight corruption, negative repercussions might also be incurred by diminishing the ability of governments to promote extra-commercial, such as environmental or labour, standards in investment²².

The central provision in the text of the TRIPS agreement is a minimum copyright and patent term of 20 years²³ (although some LDCs have impact delays of 10 or 20 years). This provision faced challenge by developing countries over the likely price effect on generics, especially with regards to HIV antiretrovirals, which eventually led to the Doha Declaration in 2001. This indicated that TRIPS should be suspended for the relevant medicines required to protect public health, and gave flexibility to the implementation of IP rights. However, a report by the World Health Organisation in 2011 found that most developing countries had not incorporated the Doha flexibilities into their IP law, owing to lack of information and legal resources, as well as complications thrown up by parallel investment treaties²⁴

The Agreement on Technical Barriers to Trade (TBT) (meaning domestic regulations unrelated to tariffs) allows domestic regulations to set standards that are higher than agreed trading standards if they can be justified on environmental or public health grounds. It is of note that France used TBT successfully in 2001 to defend its ban of asbestos imports, after being challenged by Canada. Proponents of TTIP argue that given that the TTIP is aligned to these TBT provisions, there would appear to be scope for national standards to be set at a higher than the prevailing level as long as this can be justified on such grounds²⁵.

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) has, in the evidence review, been shown to weaken the precautionary principle by mandating a scientific risk assessment on all regulatory standards. It allowed Canada and the US to impose sanctions to the value of \$150m on the EU in 1998, in retaliation for the EU's long-held ban on hormone-treated beef imports, as there was insufficient scientific evidence to support the ban. This matter has been subsequently resolved by facilitating increased quotas for non-hormone treated US and Canadian beef²⁶.

The Agreement on Government Procurement (AGP), which is plurilateral, requires governments to take social policy objectives into account when selecting between tenders. There are questions raised in the literature review over the desirability of empowering extra-commercial objectives, as these may be used to disguise political agendas²⁷.

²²Salzman, (2000) 'Labor rights, globalization and institutions: the role and influence of the Organization for Economic Cooperation and Development'

²³ See articles 9 and 33 of the TRIPS agreement, http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm

²⁴<http://apps.who.int/medicinedocs/documents/s21425en/s21425en.pdf>

²⁵ <http://www.kommers.se/Documents/dokumentarkiv/publikationer/2014/TTIP-snabbrapport-eng.pdf>

²⁶ p.100, 'The Transatlantic Collasus',

<http://www.collaboratory.de/images/archive/8/8d/20140116221236!TheTransatlanticColossus.pdf#page=100>

²⁷ <http://www.unpcdc.org/media/132243/ox.pdf>

3.6 **Effectiveness of WTO agreements and the public health exemptions**

With the exception of AGP, these programmes along with GATT are the mandatory and founding agreements of the WTO, so the majority of countries are party to them. They are enforced by a country-to-country dispute settlement mechanism. Hence, their use may be shown by the rise in international trade disputes facilitated by the WTO as compared with GATT previously, from an average of three per year with GATT to 25 cases per year with the WTO²⁸.

The WTO agreements prohibit policies that are demonstrated to be purely protectionist. Those of a purely public health motivation are likely to be upheld by the TBT or SPS agreement, and to a lesser extent by the Doha declaration. However, the vast majority of cases have fallen in between the categories, and the tendency of arbiters in this situation has consistently been to claim the policy in question illegal on the basis of protectionist intention. This is of concern as it is not always possible to separate protectionism from public health concerns.

There have been complaints in the literature that the health exemption provisions are too complex or costly for implementation, making for “regulatory snare” in some cases. In other cases, “regulatory chill” has come into play (whereby policy makers reduce policy space in the erroneous belief that certain policies are illegal).

3.7 **Bilateral investment treaties in the European Union**

The European Union is the most developed example of a regional FTA, and thus has a host of legal frameworks that also impact on the ability of governments to act in the area of public health. Beyond the fundamental legal framework allowing the free movement of capital, labour, goods and services, discrimination is prohibited in areas such as government procurement and investment.

EU regulatory law has considerable reach over product safety, labelling and marketing. For example, it includes directives that prohibit the direct-to-consumer advertising of prescription-only pharmaceuticals, and the advertising of tobacco on television²⁹.

Bilateral investment treaties (BITs) became common between Western Europe and Central and Eastern Europe during the 1990s. They give increased protection to foreign investors. The accession of the 12 new member states in the 2000s brought these BITs alongside EU law; currently, there are an estimated 190 intra-EU BITs, out of the 1500 EU-based BITs. Altogether, countries in Central and Eastern Europe have been sued at least 77 times whereas there have only been seven cases in Western Europe³⁰.

The Lisbon Treaty that was has provided additional new powers for the EU to directly negotiate Foreign and Domestic Investment (FDI) treaties and has additionally

²⁸ http://www.wto.org/english/res_e/booksp_e/historywto_07_e.pdf

²⁹ Directives 2001/83/EC and 89/552/EEC, respectively

³⁰ http://www.tni.org/sites/www.tni.org/files/download/briefing_on_intra-eu_bits_0.pdf

provided that the European Parliament must approve FTAs to be ratified³¹. CETA and TTIP represent two significant new FTAs being negotiated following the signing of the Lisbon Treaty.

3.8 **International Health Law**

The World Health Organisation (WHO) is another post-war institution established to aid global governance. Its role is to provide leadership on public health matters. Its relevance to international trade is in the setting of prudent norms and standards, the basis of which is article 25 of the Universal Declaration of Human Rights.³² WHO sets out its trade agenda as follows:

“WHO works to achieve greater policy coherence between trade and health policy so that international trade and trade rules maximize health benefits and minimize health risks, especially for poor and vulnerable populations.”³³

The aim of WHO, and international health law generally, is to help support the provision of health policy space.

An example of this aim being realised is the 2003 WHO Framework Convention on Tobacco Control (FCTC). FCTC sets out minimum standards governing the production, distribution, marketing and taxation of tobacco under a progressive agenda. It has been ratified in 179 countries, including all EU states but not the US.³⁴ A report in 2010 noted that the treaty had made considerable impact, with the vast majority of parties implementing remedies such as tobacco education programmes, large health warnings on packaging and advertising bans.³⁵

The FCTC is the first of its kind – a multilateral, binding agreement setting minimum regulation standards regarding non-communicable disease. Agreements on other issues such as childhood obesity are currently subject to discussion. According to WHO, the number of obese children under five will come close to doubling in the period 2012-2025 if current trends continue.³⁶ A WHO commission was recently set up to address the problem, and identified several areas of concern including the advertising of unhealthy foods aimed at children.

3.9 **Summary Assessment**

The alignment between public health goals and trade liberalisation goals has not always been clear. Initiatives such as the FCTC have demonstrated the potential of international law to address issues relating to NCDs. The current WHO campaign on childhood obesity is likely to be pivotal, most particularly where it moves from education to regulation. How well placed international governance structures are to mediate a

³¹ http://trade.ec.europa.eu/doclib/docs/2011/june/tradoc_147977.pdf

³² “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services....”

³³ http://www.who.int/trade/trade_and_health/en/

³⁴ http://www.who.int/fctc/signatories_parties/en/

³⁵ <http://www.who.int/bulletin/volumes/88/2/10-075895/en/>

³⁶ <http://www.who.int/dietphysicalactivity/end-childhood-obesity/en/> (from 40m in 2012 to 70min 2025)



process of engagement between public and business interests will be instrumental in determining the extent to which international trade and health law can be aligned. These issues have a significant impact on agreements such as TTIP as they can underpin or provide challenge to them, an issue that is returned to in the final sections of this report.

4.0 Economic Impact

The overall potential economic benefits of TTIP are largely projected to come from non-tariff based reform. Projected benefits have been subject to empirical challenge, and reference to other FTAs indicates impact is difficult to assess and that all projections should be treated with caution.

The development of TTIP has been structured in three parts, each of which broadly accord with the themes considered in the previous chapter on FTAs.

- 1) Market Access, which focuses on removing custom duties on goods and restrictions on services, gaining better access to public markets, and making it easier for foreign investment. Themes include:
 - Goods, including market access and rules of origin; and
 - Services and Investment, ranging from regulation of financial services to ISDS.
- 2) Industry-specific regulation: which aims at delivering regulatory coherence and cooperation, and is focussed on eliminating or reducing regulatory barriers such as bureaucratic duplication of effort. Chapters include:
 - Horizontal chapters: such as regulatory coherence and technical barriers to trade; and
 - Specific sectoral agreements: including pharmaceuticals and medical devices.
- 3) Broader rules and principles and modes of co-operation which focus on improving cooperation in relation to international standards, with chapters on:
 - Public procurement;
 - Intellectual property; and
 - Competition policy including treatment of state owned companies.

4.1 Economic Impact

At the heart of free trade liberalisation is the normative belief that such reform will have a positive economic benefit. The European Commission as part of the development process has commissioned a number of economic studies which support this belief. The Centre for Economic Policy Research (CEPR) study for instance predicts that an ambitious TTIP deal would increase the size of the EU economy by around €120 billion (or 0.5% of GDP) and the US by €95 billion (or 0.4% of GDP)³⁷³⁸. This would be a permanent increase in the amount of wealth that the European and American economies can produce every year. The CEPR study uses a computable general equilibrium (or CGE) model to simulate the impact of TTIP. These are standard tools for trade economists that create a computerised simulation of the world economy and model what happens when changes are introduced.

Providing a broader framework for assessing benefits realisation has proved to be more challenging. To take the example of NAFTA as the most significant multilateral FTA to be negotiated by the United States, it is apparent that there has been significant disagreement regarding the extent to which there have been manifest benefits accrued

³⁷ http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf

³⁸ http://trade.ec.europa.eu/doclib/docs/2013/september/tradoc_151787.pdf

as a result of its implementation, what harms have been caused and the dynamics of these as well as any overall cost benefit assessment.

A March 2014 report commissioned and financed by the Confederal Group of the European United Left/Nordic Green Left (GUE/NGL) political group in the European Parliament published by ÖFSE (Austrian Foundation for Development Research) examined a range of studies that have been commissioned to consider the potential impact of TTIP, including Ecorys (2009), CEPR (2013), CEPII (2013) and Bertelsmann/ifo (2013). The ÖFSE study broadly confirm growth projections although it argues that the 80% of total TTIP benefits to be 'overly optimistic'³⁹. The report also contends that projected gains in terms of increased exports could be matched or exceeded by the impact of revenue losses and direct and indirect costs resulting from short term growth in unemployment. Of particular relevance to the public health debate the report also challenges the estimated gains due to the removal of non-tariff barriers (NTBs).

The fundamental challenge in seeking to validate these estimates is that they are based not on comparative data drawn from the realised benefits achieved by existing FTAs, but on the basis of a simulation exercise. CGE models have been subject to significant challenge, not least from civil society organisations. Whilst it is not within the remit of this study to consider in depth the challenges to CGE modelling, it is important to highlight the fundamental challenges of such an approach and most particularly their dependence on the veracity of the assumptions that underpin them. As a 2006 Oxfam funded study comments:

"CGE models can be useful quantitative supplements to experimental thinking about the importance of different potential causal linkages among economic variables at the country or world level. However, mechanically churning out 'projections' of welfare gains or any other indicator subject to one single set of causal assumptions and parameter values is a fundamental misuse of a sometimes helpful tool."⁴⁰

In general the economic assessments have generally drawn conclusions that aligned to the aims of their sponsoring bodies. Fully independent studies have been more difficult to identify. However a Global Development and Environment Institute Working Paper from October 2014 by Jeronim Capaldo at Tufts University presents a negative assessment of the potential economic impact of the TTIP⁴¹. Using the United Nations Global Policy Model, which incorporates different assumptions on macroeconomic adjustment, employment dynamics, and global trade to CGE modes, the study concludes that TTIP would lead to a contraction of GDP, personal incomes and employment. The study also projects an increase in financial instability and a continuing downward trend in the labour share of GDP.

4.2 **Employment, Wages & Productivity**

Not only do the CGE-based studies identify overall economic benefits as being likely to accrue from TTIP, but they also identify direct benefits in terms of increased employment, wages and productivity. A study commissioned by the Bertelsmann

³⁹ http://guengl.eu/uploads/plenary-focus-pdf/ASSESS_TTIP.pdf

⁴⁰ Modelling the Impact of Trade Liberalisation, Oxfam International Research Report, July 2006

⁴¹ <http://www.ase.tufts.edu/gdae/Pubs/wp/14-03CapaldoTTIP.pdf>

Foundation, an organisation which is broadly supportive of TTIP contends that for Germany alone:

“A TTIP would benefit the entire (German) economy. Many new jobs would be created in the manufacturing industry, especially in the electronics industry and metal processing. Non-export oriented industries in the service sector would also benefit indirectly from an agreement through inter- and intra-sector relationships.”⁴²

It is of note that the report also states that “because of the relatively high sector-specific impact, low-skilled individuals would also be subjected to more changes than medium or highly qualified”⁴³. However it should be noted that the Bertelsmann Foundation is a private operating foundation committed to the view that competition and civic engagement are essential for social progress.

A particularly informative debate in the UK House of Lords Select Committee in May 2014 highlighted the views of a range of stakeholder groups. It was evident from these that trade unions have differing views on the potential impact of TTIP. Whilst there was recognition of the potential positive impact on jobs, concern was expressed about the potential movement of jobs to the US, although other experts cited the relatively higher wage levels in the U.S. as being one reason that such movement would be unlikely.

A University of Toronto Canadian Institute for Advanced Research (CIAR) and National Bureau of Economic Research (NBER) report on the Canada-US FTA by Daniel Trefler began to identify short and long term trends that related to both employment and productivity⁴⁴. The findings are that where there are tariff reductions, then there is an impact on productivity in that it increases as less productive capacity is reduced. However, the report also found that the impact on employment is more problematic to determine, and that employment levels can fall as well as increase as a result of their introduction.

It is also important to differentiate between FTAs and the underlying economic position of contributing countries. With this in mind the traditional view is of FTAs between MDCs and LDCs is that under an FTA the latter lose employment to the former. A regularly voiced stakeholder view from the US regarding NATFA is that it had significant and negative impact on employment and wage levels. However, the Council on Foreign Relations (CFR, an independent, nonpartisan think tank that receives significant corporate financial support, reports that many economists agree NAFTA has caused some overall improvement in U.S. jobs, but at the cost of short term fluctuations that have impacted on employment levels.

Studies that have focussed not just on MDC to MDC FTAs but to those involving the US and EU suggest a more benign impact on employment. A further European Commission funded study undertaken by the Ecorys consultancy stated that real wages follow the same pattern as national income, resulting in the highest real wage

⁴² Bertelsmann Stiftung Future Social Market Economy Policy Brief May 2013

⁴³ op cit

⁴⁴ D Trefler (2006) The Long and Short of the Canada-U.S. Free Trade Agreement University of Toronto Canadian Institute for Advanced Research (CIAR) and National Bureau of Economic Research (NBER)

increases under the EU-US FTA. The same study also found that developments in real wages are similar for unskilled and skilled labour⁴⁵.

4.3 **Impact on Less Developed Countries**

A report by CARIS, University of Sussex for the Department for International Development on the potential impact of TTIP on LDCs highlighted some areas of risk particularly in relation to trade between LDCs and the EU, but drew the overall conclusion that key sectors for such countries such as textiles were unlikely to be substantially impacted by TTIP⁴⁶. Other reports such as that by ÖFSE do highlight other potential areas of concern for developing countries but the overall potential impact in relation to trade should be assessed as meaningful but not highly impactful. What has been noted by the CARIS study is that LDCs have not been included within the decision making process and as such have not been able to make the case for alignment in respect of issues such as standards and testing of goods and produce.

4.4 **Summary Assessment**

The principal area of economic benefit from TTIP to the EU is predicted to emanate from non-tariff based regulatory reform. At around €120bn the magnitude of impact is not insignificant although the strength of recent empirically based challenges should not be underestimated. Equally, to help locate the discussion within the public health realm one can cite a 2012 Centre for Addition and Mental Health report by Jürgen Rehm and Kevin Shield that states that the social costs of alcohol consumption for the year 2010 could amount to €155.8 billion⁴⁷. Whilst the study does not directly consider the impact of regulatory public health intervention in this field, it is evident that the value magnitude of just one public health issue bears comparison with the potential direct economic gains that are projected to accrue from TTIP.

⁴⁵ ECORYS 2009 The impact of Free Trade Agreements in the OECD

⁴⁶

http://tradesift.com/Reports/Potential%20Effects%20of%20the%20Proposed%20Transatlantic%20Trade%20and%20Investment%20Partnership%20on%20Selected%20Developing%20Countries_DFID_Final%20Report_July2013.pdf

⁴⁷ http://amphoraproject.net/w2box/data/AMPHORA%20Reports/CAMH_Alcohol_Report_Europe_2012.pdf

5.0 Health Impact

Health Impact will be felt across goods and services, in food, pharmaceuticals and the delivery of health services. Few defined benefits could be identified. Identified disbenefits were also limited, although the scale and impact of these is likely to be dependant on a highly complex interplay of factors.

For presentational purposes this report considers these issues on a thematic basis covering those issues that evidence suggests could have greatest impact within the health domain:

- Trade in goods
- Technical barriers to trade (TBT)
- Sanitary and Phytosanitary (SPS) Issues
- Trade in Services
- Dispute Resolution; and
- Intellectual Property

5.1 Trade in Goods

The EU and US already have one of the lowest levels of tariffs, and relative to other FTAs tariff reduction cannot be said to be the dominant part of TTIP, as it represents only 20% of the overall projected value to be realised from its implementation.

TTIP is anticipated to increase US investment into the European Union and as a consequence could lead to reduced consumer prices and increase choice. Generally FTAs involve zero tariffs for foods although there are transition periods such as the seven-year period for grain provided for in CETA. Where particular issues cannot be resolved then FTAs may agree to put issues into the 'long grass. One such as example of this is the US-Australia FTA that includes provision to review labelling of GM in the future⁴⁸.

5.1.1 Agri-Food

Health will be impacted by tariff reductions as processed foods would account for the single largest increase in import of goods by sector (2.37%), which may in turn impact on reducing the price of unhealthy foods within the EU, thereby affecting diet and health.

The European Union is the world's leading processed food exporter, with roughly twice the exports of the United States. EU exports of processed food products reached \$91 billion in 2012, growing 28% over five years⁴⁹. As such the EU remains the larger exporter of processed foods, but following the overall logic of FTAs one would expect a reduction in tariffs to result in an increase in trade and a reduction in prices. Were this to happen in the EU, a significant proportion of such products would likely be high in sugar, salt and saturated fats. Given that there is already a good deal of focus being

⁴⁸ <http://www.bilaterals.org/?australia-us-free-trade-agreement>

⁴⁹ <http://www.fas.usda.gov/data/us-processed-food-exports-growth-outlook>

put onto the issue of unhealthy foods by the public health community, one can see that TTIP could have the impact of exacerbating the situation by facilitating a reduction in the market price for such goods and thereby an increase in uptake and consumption.

A number of studies have sought to establish the relationship between price and demand for unhealthy food, with many reporting a significant effect⁵⁰. For example, in a paper for PLOS Medicine (an open-access medical journal), David Stuckler and colleagues have established a correlation between US FTAs and an increase in some unhealthy foods (soft drinks) in LDCs⁵¹. On this basis, it would be possible to establish an overall potential effect for TTIP in relation to a reduction in the price of unhealthy foods, although no such study has been undertaken to date. The overall impact of increased market access on public health is therefore more difficult to establish.

The same issue could apply to alcohol, where there is again an expectation of reduced tariffs and increased imports. As a reference the CETA agreement will eliminate all import tariffs on spirit alcohols and wines. Indeed, both industry groups Spirits Canada and Spirits Europe see the potential for growth in Europe and Canada respectively. Spirits Canada have said that they expect to double their exports to Europe, targeting in particular Eastern Europe. Whilst the position regarding tariffs on alcohol between the US and Europe are different, TTIP clearly represents a potential challenge to alcohol control policies if its implementation results in reductions in price and increase in supply.

If this is the case, then public health bodies may seek to use a number of regulatory instruments to offset any detrimental health impact. Concern has been raised by a number of public health stakeholder groups that the TTIP could make such a regulatory response more difficult to achieve. This issue is discussed further in the Health Policy chapter of this paper.

5.2 **Technical Barriers to Trade**

The OECD defines technical barriers to trade (TBT) to be technical regulations, minimum standards and certification systems for health, safety and environmental protection and to enhance the availability of information about products, which may result in the development of TBTs⁵². There are a plethora of organisations such as ISO that work on producing international standards, but the situation remains that there is significant variation in relation to standards and to compliance regimes. The WTO addressed this issue at the Uruguay Round of GATT with the development of the TBT Agreement.

The TBT Agreement that came into force in 1995 is binding on all WTO members and the focus more recently has been to draw upon the principles and guidelines when developing FTAs such as TTIP. The two most important principles underlying these negotiations relate to standards and compliance, and the interpretation of both could have a marked impact on public health.

⁵⁰ D, Talukdar & C, Lindsey (2013) To Buy or Not to Buy: Consumers' Demand Response Patterns for Healthy Versus Unhealthy Food Journal of Marketing: March 2013, Vol. 77, No. 2, pp. 124-138

⁵¹ <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001235#pmed.1001235.s007>

⁵² <http://stats.oecd.org/glossary/detail.asp?ID=2683>

In an initial discussion document circulated by the European Commission, a basic framework for TBT negotiations in TTIP has been set out. The documents states at an early juncture that:

“First, as far as possible, measures should aim at removal of unnecessary barriers to trade arising from differences in the content and application of technical regulations, standards and conformity assessment procedures.”⁵³

A position paper by CEN (European Committee for Standardisation) and CENELEC (European Committee for Electrotechnical Standardisation) is supportive of TTIP and its TBT provisions, but it does note that “...not only the interpretation of “convergence to international standard” is different on both sides of the Atlantic, but also the understanding of “transparency and predictability of regulatory and standards setting processes”⁵⁴.

A 2013 paper by the Center for International Environmental Law, which declares its aims to be to promote human health and ensure a just and sustainable society, sets out four concerns relating to regulatory convergence. It contended that TTIP could restrain the continued development of stronger laws in the EU and that it may pre-empt stronger sub-regional laws by Member States. The paper also contends that TTIP could weaken developing standards for human health, labour and the environment in both the EU and US, such as those relating to nanomaterials and endocrine disruptors. It could also influence the development of regulations and standards outside the EU and US, including countries with economies in transition that have recently adopted environmental policies more similar to European than American approaches⁵⁵.

The early rounds of TTIP negotiations resulted in a European Union proposal to establish a joint EU-US oversight body for the development of regulations in the two regions. This “Regulatory Cooperation Council” would consist of the heads of the most important EU and US regulatory agencies, monitor the implementation of commitments made, and consider new priorities for regulatory cooperation. This appears to suggest that there would be an on-going commitment towards regulatory cooperation, not least given the proportionate value attached to regulatory over tariff reforms in TTIP.

5.2.1 **Pharmaceuticals**

The treatment of pharmaceuticals within the TBT chapter of TTIP is of particular importance from a health perspective, with proponents believing that it will elicit significant benefit but critics believing that it could have a detrimental impact not least with respect to medicines’ affordability. As Leigh Hancker has contended in a 2010-edited book on Health Systems Governance in Europe, “the twin tracks of ‘regulatory’ and ‘market’ pathways are intersecting in new and challenging ways for the major stakeholders in the European Union”⁵⁶.

⁵³ EU - US TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP Technical barriers to trade Initial EU position paper (http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151627.pdf)

⁵⁴ CEN – European Committee for Standardization and CENELEC – European Committee for Electrotechnical Standardization Position Paper on EU-US Transatlantic Trade and Investment Partnership (TTIP) – Technical Barriers to Trade – Initial EU Position Paper

⁵⁵ Center for International Environmental Law (2013) Trans-Atlantic Trade and Investment Partnership (TTIP) Monitor

⁵⁶ <http://apps.who.int/medicinedocs/documents/s21372en/s21372en.pdf>

Pharmaceuticals represent an important industry sector for US and EU policy negotiators, with those in Europe in particular seeking to address a range of pressing market and public health related issues:

“Europe’s industry, rightly or wrongly, is hence perceived by the sector, as well as policy-makers at the European level, to be facing serious challenges, matched only by those facing public health, challenges driven by demographic change and the high cost of innovative treatments.⁵⁷”

Despite these challenges, the Economist Intelligence Unit anticipates that by 2016 the developed European pharmaceutical market will have recovered the sales value lost since 2008, and that by 2017 it will have exceeded it⁵⁸.

It is generally acknowledged that most if not all the European Union have to date enjoyed relatively good standards of affordable medicines supply, even though levels and costs of both generic and branded medicines usage are variable. The mix of public and private pharmaceutical purchasing systems and the economic wealth of different European Member States means that access to medicines across the EU is by no means homogenous.

Since the 1990s pharmaceutical spending as a proportion of GDP has, in line with healthcare, generally increased in every European Member State (with the exception of Luxembourg)⁵⁹. The OECD estimates that during the first decade of the current century average European spending per capita on pharmaceuticals has risen by almost 50% in real terms⁶⁰. Within the context of the global economic crisis, a range of initiatives have been introduced to constrain pharmaceutical costs, including price reductions and changes in co-payments, VAT rates on medicines and distribution margins⁶¹. Despite these initiatives there is evidence that access to medicines in a number of European countries remains problematic⁶².

Pharmaceutical industry associations assert that the TTIP offers significant opportunities to reduce regulatory burden, transaction costs and the time it takes to get new medicines to market. One assessment of the benefits offered by TTIP that was posted on the official blog of Eli Lilly and Company is that it could improve access for patients to innovative medicines, support jobs in the European and US pharmaceutical industries and be an appropriate benchmark for future trade agreements with other countries⁶³.

This illustrative source contends that this would be achieved by means of regulatory harmonisation between the European Medicines Agency (EMA) and the Food and

⁵⁷ <http://apps.who.int/medicinedocs/documents/s21372en/s21372en.pdf>

⁵⁸ https://www2.deloitte.com/content/dam/Deloitte/dk/Documents/life-sciences-health-care/European_austerity.pdf

⁵⁹ http://ec.europa.eu/economy_finance/publications/economic_paper/2012/pdf/ecp_461_en.pdf

⁶⁰ [http://www.oecd-](http://www.oecd-ilibrary.org/docserver/download/8110161ec045.pdf?expires=1417430147&id=id&accname=guest&checksum=9C182BC9F71B6C3A612E2957FB0AF250)

[ilibrary.org/docserver/download/8110161ec045.pdf?expires=1417430147&id=id&accname=guest&checksum=9C182BC9F71B6C3A612E2957FB0AF250](http://www.oecd-ilibrary.org/docserver/download/8110161ec045.pdf?expires=1417430147&id=id&accname=guest&checksum=9C182BC9F71B6C3A612E2957FB0AF250)

⁶¹ <http://apps.who.int/medicinedocs/documents/s19046en/s19046en.pdf>

⁶² http://www.oxfam.org/sites/www.oxfam.org/files/file_attachments/bp-trading-away-access-medicines-290914-en.pdf

⁶³ <http://lillypad.eu>

Drug Administration (FDA) that would reduce unnecessary duplication and pave the way for the development of global standards. Mutual recognition of inspections negotiated in TTIP would be based upon the Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP) inspections. The current programme of parallel scientific advice may also be expanded to cover all medicines, enabling companies to pursue applications in both the EU and US and to conduct clinical trials based on a common approach. Such an approach finds further support in a joint EFPIA and PhRMA trade association position paper on TTIP⁶⁴.

The European Consumer Organisation (BEUC) also recognised that TBT is likely to play an important role and that in the area of harmonisation of GMP and GCP procedures, pharmaceutical practices could be improved⁶⁵. Yet BEUC also expresses concerns relating to the expansion of parallel scientific advice within the ‘definition of commercial confidentiality’ whereby clinical trials reports could be deemed commercially confidential. This could stymie progression towards greater transparency of clinical trial data as set out in the new Clinical Trials Directive.

In relation to pricing and reimbursement EFPIA the European pharmacy trade association has argued that TTIP should:

“...include a Pharmaceuticals Annex similar to that included in the EU and United States’ free trade agreements with Korea to ensure transparent, timely and predictable pricing and reimbursement processes that provide applicants with meaningful due process.”⁶⁶

This is one of a number of issues highlighted in a ‘leaked memo’ of priorities for the Pharmaceutical industry circulated by the TransAtlantic Consumer Dialogue (TACD). In relation to pricing and reimbursement the document states that “when external reference pricing, only countries that are similar in terms of their socio-economic level, purchasing power, populations, disease burdens and health care system should be taken into account; bailout countries while they are undergoing fiscal restructuring programmes should be excluded from any referencing.”⁶⁷

The European generics industry also supports the development of TTIP and has set in place its own priorities, which include a regulatory framework allowing single EU/US development programmes for generic and biosimilar medicinal products and convergence of data requirements for their approval in the EU and the US as well as a regulatory framework allowing advanced manufacturing for export purposes⁶⁸.

The potential for FTAs to materially impact on pharmaceutical prices have also been established in other countries such as Australia. A paper written for Globalization and Health at the early stage of the Australia-US FTA negotiation process commented on the inclusion of a range of similar non-tariff reforms to those being considered in TTIP. The paper contends that:

⁶⁴ http://www.efpia.eu/uploads/documents/EFPIA_PhRMA_TTIP_Online.pdf

⁶⁵ <http://www.beuc.eu/blog/how-will-ttip-affect-the-health-of-europeans/>

⁶⁶ http://www.efpia.eu/uploads/documents/EFPIA_PhRMA_TTIP_Online.pdf

⁶⁷ <http://tacd-ip.org/archives/1138>

⁶⁸ http://trade.ec.europa.eu/doclib/docs/2013/june/tradoc_151372.pdf

“The potential exists for the AUSFTA to reshape the character of Australia's regulatory system concerning medicines from a public good- to a private rights-oriented system. Should the AUSFTA precipitate such a normative shift (particularly one away from scientific cost-effectiveness evaluation of pharmaceuticals) the regulatory implications are likely to be profound and resonate beyond Australia to impact on the health care sectors of other nations⁶⁹.”

Enhancing the competitiveness of Europe's pharmaceutical sector remains a strategic priority for the European Commission and TTIP provides an important means to help achieve this goal. Reconciling this market goal to the regulatory goal of ensuring access to medicines for Europe's 500 million citizens will continue to form an important element of the current TTIP negotiations, with on-going attention to the detail under consideration required from all interested stakeholder groups.

5.2.2 **Agri-Food**

The potential for the TBT chapter to impact on agri-food has been highlighted in the literature on the TTIP, although there is far less comment on the subject when compared with the issue of food safety. There are examples of how other FTAs have impacted on the achievement of broader public health goals such as those related to reductions in NCDs and how TBT issues have impacted upon this process.

One relevant comparison from Chile has been highlighted in Nutritional Outlook, a resource for the manufacturers of dietary supplements and healthy food and beverages⁷⁰. The paper considers Chile's new law “Nutritional Composition of Nutrients and Their Advertising” as being the first in the world to require label-warning statements on foods high in fat, sugar, and salt. The legislation also expands what must be listed on nutrition labels including reference to saturated fats, sugars, calories, protein, carbohydrates, and sodium content. It is proposed that this will then be extended to include nutrient profiles⁷¹. Further elements of the proposed policy would require some foods to include labels advising consumers to avoid excessive intake of certain foodstuffs and would extend to changes in the regulation of food advertising, particularly where this currently targets children.

Chile has 59 existing bilateral and regional trade agreements with countries including the European Union and the United States. This research study did not find examples of action currently being taken under the provisions of these, however during a meeting of the World Trade Organization's (WTO's) Technical Barriers to Trade (TBT) Committee, several member delegations expressed concerns about Chile's proposed food health regulation amendments. Representatives from countries including the United States and the European Union contended that such requirements were not based on relevant Codex nutrition labelling guidelines and as such that they would

⁶⁹ Faunce, T. (2005) Assessing the impact of the Australia-United States Free Trade Agreement on Australian and global medicines policy

⁷⁰ <http://www.nutritionaloutlook.com/about>

⁷¹ <http://www.nutritionaloutlook.com/article/global-regulations-chile's-new-law-high-fat-sugar-salt-warnings-3-10233>

create unnecessary barriers to international trade. They also contend that the provisions had not been properly brought before the TBT Committee⁷².

Whilst tax is not a technical barrier to trade the current example of Mexico provides a interesting case study in agri-food. In this particular case the NAFTA FTA resulted in a significant reduction in tariff levels on soft drinks. Evidence has directly linked the FTA to an increase in the consumption of high sugar content drinks and a rise in obesity levels⁷³. Yet following significant pressure from public health stakeholder bodies, the Mexican Government has recently introduced a tax on such drinks⁷⁴. The most recent evidence suggests that the tax has resulted in a reduction in consumption of around 10%⁷⁵. That having been said the same article confirms that investment levels by US soft drink manufacturers continues to grow, with only limited commitments to market lower sugar and sugar free alternative products.

Given that over a third of the cases brought to the WTO have involved food⁷⁶ it is likely that this will be an area of particular focus in relation to TTIP, although once again it should be stressed that consideration should be viewed within the wider context of regulatory provisions provided at an international as well as a regional and national level.

5.2.3 **Summary Assessment**

Health related TBTs primarily relate to pharmaceuticals and agri-food. The removal of TBTs could positively impact on health if pharmaceutical prices fell as a result of regulatory efficiencies being realised and innovative medicines getting to the market more quickly. Yet such benefits could be offset by concomitant increases in pharmaceutical costs resulting from other provisions within the TBT chapter. Equally whilst the risk to areas such as agri-food labelling maybe further impacted by provisions with the TBT chapter of TTIP, evidence suggests that governments have been able to seek to mitigate negative impacts by introducing new public health regulation.

5.3 **Sanitary and Phytosanitary (SPS) Measures**

The WTO defines SPS as regulatory measures that seek to protect human or animal life from risks arising from additives, contaminants, toxins or disease-causing organisms in their food, beverages, feedstuffs; human life, plant as well as animal-carried diseases, animal or plant life pests, diseases, or disease-causing organisms⁷⁷. From such a perspective SPS related agri-food issues are likely have the greatest health consequence.

⁷² op cit.

⁷³ <http://civileats.com/2013/07/17/mexico-public-health-rising-obesity-and-the-nafta-effect/>

⁷⁴ <http://www.theguardian.com/world/2014/jan/16/mexico-soda-tax-sugar-obesity-health>

⁷⁵ <http://online.wsj.com/articles/survey-shows-mexicans-drinking-less-soda-after-tax-1413226009>

⁷⁶ Bronkers, M and Soopramanien R (2008) The Impact of WTO Law on European food regulation European Food and Feed Law Review 361

⁷⁷ http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c1s3p1_e.htm

Exports from the U.S. of agricultural products to EU countries totalled \$11.9 billion in 2013. The EU countries together would rank fifth as an agricultural export market for the United States. Leading categories include: tree nuts (\$2.3 billion), soybeans (\$1.5 billion), soybean meal (\$860 million), wine and beer (\$649 million), and prepared food (\$492 million)⁷⁸. U.S. imports of agricultural products from EU countries totalled \$17.6 billion in 2013. The European Union ranks third behind Canada and Mexico as a supplier of Agricultural imports to the United States. Leading categories include: wine and beer (\$5.2 billion), essential oils (\$2.2 billion), snack foods (including chocolate) (\$1.3 billion), vegetable oils (\$955 million), and processed fruits and vegetables (\$939 million). Food makes up £19.5bn or 10% of all current US FDI to the UK alone, which is the third most important sector after financial services and information and communication⁷⁹.

Health will be impacted by provisions relating to food within TTIP, with a particular focus on the food standards and food inspection regimes. Whilst there is on-going debate regarding the merits of systems that have marked differences, it is worthy of note to compare current levels of harm related to food in the US and Europe. The Centers for Disease Control and Prevention (CDC) estimates that each year roughly 1 in 6 Americans (or 48 million people) gets sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases⁸⁰. By comparison the European Union had 48,964 cases and 46 deaths in 2009, the most recent year tallied⁸¹. Yet establishing a clear baseline position is not straightforward as a further study considers there to be relatively little difference between the two trading blocs with regard to food borne illness. A recent comparative study by The Acheson Group, LLC (TAG), led by Dr. David Acheson found that on the illness rates that the US has lower levels across a group of the most common food borne illnesses than in the EU⁸².

Food standards and regulation represent an important element of FTAs, with significant efforts put into supporting broader market access across signatory countries. The principle approach to food standards is to ensure that a framework for mutual recognition is introduced that will facilitate improved market access. This does not in itself provide an ex-ante case of regulatory dilution, but the very practicalities of allowing for minimum regulatory requirements could be viewed to be problematic within a public health realm.

Both the European and US systems have faced recent challenges. In the US Robert Tauxe, the deputy director of the CDC's Division of Foodborne, Bacterial and Mycotic Diseases has stated:

“We recognize that we have reached a plateau in the prevention of foodborne disease, and there must be new efforts to develop and evaluate food-safety practices from the farm to the table.”⁸³

⁷⁸ <http://www.ustr.gov/countries-regions/europe-middle-east/europe/european-union>

⁷⁹ Poulsen et al Costs and Benefits of an EU-USA Investment Protection Treaty, April 2013

⁸⁰ <http://www.cdc.gov/foodborneburden/trends-in-foodborne-illness.html>

⁸¹ <http://www.scientificamerican.com/article/food-poisonings-hidden-legacy/>

⁸² <http://achesongroup.com/2014/03/foodborne-illness-us-eu-compare/>

⁸³ <http://www.forbes.com/sites/henrymiller/2011/06/01/europes-food-poising-outbreak-reaping-what-it-has-sown/>

What this suggests is that in the US as in Europe there are increasing challenges with respect to meeting consumer demand for agri-food whilst ensuring that food safety issues are addressed. The SPS chapter of TTIP is predicated upon a commitment to ensure food safety, but agreement on the best means to achieve this are yet to be reached.

5.3.1 Food Safety

Food safety and inspection standards in the US and EU are based upon fundamentally different regulatory principles with differences manifesting themselves in relation to where, when and how products are subject to regulatory assessment.

The varying approach to food standards is illustrated well by the issue of irradiation. Whilst foodstuffs are subject to irradiation on both sides of the Atlantic, it has been an issue that has raised significant concern within sections of stakeholder opinion. Organisations such as the Center for Food Safety argue that TTIP would lead to a significant increase in food irradiation, which it argues has significant health disbenefits. A recent report states that:

“Food irradiation is an after-the-fact “solution” that does nothing to address the unsanitary conditions of factory farms, and actually creates a disincentive for producers and handlers to take preventative steps in production and handling.”⁸⁴

Yet one proponent of irradiation of food states that it is another important tool, one that is safe and effective but that has been vastly under-used, largely due to opposition from the organic food lobby and to government over-regulation. According to Michael Osterholm, director of the Center for Infectious Disease Research and Policy at the University of Minnesota

“If even 50% of meat and poultry consumed in the United States were irradiated, the potential impact of food borne disease would be a reduction [of] 900,000 cases and 300 deaths.”⁸⁵

In the US the Institute for Agriculture and Trade Policy has produced two papers on the public health problems in the draft TTIP chapter on Sanitary and Phytosanitary (SPS) issues and they question whether the standards, were they to be implemented could be enforced. They draw attention to the high cost in the US of foodborne illness (“\$33 billion annually”)⁸⁶.

The example of whether imports from the United States of chlorine treated chicken would be allowable is based upon the assumption that TTIP will agree mutual recognition of existing food standards within the United States. Yet behind this issue lies a more fundamental concern regarding the principles that underpin any programme of regulatory cooperation. For foodstuffs this can be illustrated by the debate as to whether to adopt a supply chain ‘farm to table’ approach to food safety or to adopt the

⁸⁴ <http://www.centerforfoodsafety.org/issues/1039/food-irradiation/irradiation-and-food-borne-illness>

⁸⁵ <http://www.forbes.com/sites/henrymiller/2011/06/01/europes-food-poising-outbreak-reaping-what-it-has-sown/>

⁸⁶ (Hansen-Kuhn and Suppan, 2013), (Hansen-Kuhn and Suppan, 2013)

US approach, which focuses its food standards approach at a single end point in the supply chain.

A paper published in July 2014 by the Institute for Agriculture and Trade Policy (IATP) sets out the fundamental concerns with food safety as they relate to TTIP, much of which relates to SPS regulations. Simply put the challenge is that current discussions suggest that SPS is being subordinated to maximising trade⁸⁷. Dr Steve Suppan, IATP's author of the paper stated:

“While many key details regarding things like GMOs are still hidden, its clear public health is losing out to corporate interests in a big way”.

A centre for Food Safety report published in May 2014 provided further detail of the potential impact of TTIP on both sides of the Atlantic⁸⁸. The report sets out a host of difficult food products that are currently restricted in the US or the EU, which could become legal across the FTA area under the terms of TTIP.

The key part of the discussions will be the extent to which current regulatory provisions are deemed to be of ‘equivalent level’. If they are then the risk to health may be posed where evidence suggests that the US systems and cross border trade may increase health risk. There is evidence of levelling down of cross border food monitoring with a case of a Hepatitis A outbreak relating to strawberries imported from Mexico to the USA cited by many civil society bodies as demonstrating how NAFTA had led to regulatory relaxation⁸⁹.

TTIP would see the introduction of a Regulatory Cooperation Council to “converge” regulatory measures, such as food labelling requirements or environmental standards, which would be consistent with proposals offered by the U.S. Chamber of Commerce and Business- Europe.

5.3.2 **Summary Assessment**

No evidence has been found that the TTIP provisions on SPS could lead to a reduction in foodborne disease. Three potentially negative impacts on food safety have been identified. The first is that increased cross border trade in agri-food produce on the basis of mutual recognition of existing food testing arrangements could increase health risks as increased cross border trade leads to intermittent outbreaks of disease. It is difficult to estimate the potential impact of this as it would be dependant on the number and scale of any outbreaks resulting from cross border trade. It should also be noted that such incidents are also a feature of intra EU trade. The second area of risk relates to whether TTIP would seek to lift current restrictions on the importing of currently banned produce such as hormone treated beef, chlorine washed meat and genetically modified (GM) produce. Yet even if this were to happen, it is uncertain as to what the potential impact maybe as there is limited evidence on actual, as opposed to potential levels of risk. The third level of risk arises from any long regulatory pressures to converge food safety systems operating in the US and the EU.

⁸⁷ <http://www.iatp.org/documents/leaked-document-reveals-us-eu-trade-agreement-threatens-public-health-food-safety>

⁸⁸ http://www.centerforfoodsafety.org/files/cfs_trade_matters_76070.pdf

⁸⁹ cf http://www.citizen.org/trade/article_redirect.cfm?ID=1894

Yet at the heart of this discussion is whether techniques such as chlorination provide a safe, efficient and effective means to ensure food safety or whether their very use signals fundamental food safety problems across the supply chain and that a more fundamental assessment of sustainable food safety is required. The introduction of TTIP presents an opportunity to level up international food standards and to provide an enhanced platform for current pan-European work to improve food safety, yet the challenge is that such levelling up could be viewed to constitute a barrier to trade. Whether this could be addressed by framing it within a broader benefits assessment of TTIP will be based in part on being able to establish such a broader framework for assessing cost benefit.

5.4 Trade in Services

Services constitute an important aspect of TTIP and within this sector government procurement will be of particular relevance to health.

‘Public services’ is not a term used in the international trade arena. The World Trade Organization defines that only ‘services supplied in the exercise of government authority’ and only on a non-commercial basis and not in competition with other suppliers, are exempt from trade liberalisation. This narrow definition, with narrow protection, is used in trade deals such as TTIP.

Within the EU, the Lisbon Treaty divides ‘services of general interest’, – its term for public services – between ‘services of general economic interest’ i.e. essentially commercial, and ‘noneconomic services of general interest’. The latter are protected but are very few, for example, judicial services. The former, clearly potentially commercial, is almost everything including health.

The negotiations for TTIP are on-going but a helpful starting point for an assessment of these issues is the CETA between Canada and the European Union. Often cited as being in part a test ground for TTIP, it is of note that within the published Services and Investment Chapter both health and education services are excluded, and that within the Government Procurement Chapter provision is given to maintain preference for domestic providers within the health sector.

5.4.1 Public Procurement

There are a number of issues relating to health that focus more on public procurement⁹⁰. Like a number of the Chapters being negotiated within TTIP the chapter on Public Procurement is aligned to global programmes set by the WTO. There is in particular a link to the GPA provisions, with the stated ambition of helping to develop “GPA plus” elements. In relation to Public Procurement the initial EU Position Paper stated that:

⁹⁰ Services and public procurement dominate 6th TTIP round, Borderlex July 2014.

“Discussions on additional elements of coverage, such as state-owned enterprises, public undertakings and private companies with exclusive rights may require the introduction of additional definitions and related rules”⁹¹.

A central tenant of FTAs is to open markets for goods and services to greater competition and as such there is a consequent challenge faced by countries that currently protect elements of their economy. Richard Craven from Northumbria University in his paper in *Public Procurement Law Review* argues that, in the context of public procurement law, successful TTIP talks could potentially be dramatic, both for the EU and US, as well as globally⁹². The EU and US have been at the forefront of multilateral and plurilateral efforts aimed at liberalising procurement markets. Of particular interest is the contention of Craven’s that it appears to be the case that it is the EU as much or more than the US that have proved to be intent on advancing the reciprocal opening of procurement markets bilaterally. The expressed intentions are ambitious, seeking to agree a public procurement chapter that involves enhanced rules and coverage to those of the WTO Agreement on Government Procurement (GPA). Craven believes that the EU may see itself as having the most to gain, as infrastructure spending remains a focus of US economic recovery⁹³. Cited in *Borderlex.eu*, the online news service that is part of *Business New Europe*, US Chief Negotiator Daniel Mullaney however, has described this as being a ‘myth’⁹⁴.

The EU industry lobby is supportive of a broad opening up of public procurement. Business Europe set their ideas out as follows:

“Given the importance of public purchases by governments of goods, services and works, procurement commitments under the Agreement on Government Procurement of the WTO (GPA) should be expanded in terms of coverage, at all level of government and public entities, lowering the existing thresholds and ensuring transparency as well as open and predictable procedural requirements.”

Within this context one can consider the particular situation relating to health services.

5.4.2 **Health Services**

Whilst the official line from European Commission negotiators is that health services would not be impacted by TTIP there remains a clearly articulated view coming from industry and some elements of Member State governments resistant to a blanket exemption for health and keen to consider the potential benefits that could accrue to health from greater levels of market liberalisation. One of the most recent comments by a government Minister in the UK was quoted as saying that they “should be included because Britain’s healthcare industry is a major exporter and would benefit from more

⁹¹ EU - US TRANSATLANTIC TRADE AND INVESTMENT PARTNERSHIP Public Procurement Initial EU position paper 2013

⁹²

EU-US Transatlantic Trade and Investment Partnership Agreement: The European Commission's Negotiating Position on Public Procurement / Craven, Richard.

In: *Public Procurement Law Review*, 2014, issue 3, pp. NA65-NA76 (RA 634)

⁹³ Public Procurement and the EU-US Transatlantic Trade and Investment Partnership Agreement: The EU Negotiating Position Richard Craven, University of Northumbria at Newcastle

⁹⁴ Services and public procurement dominate 6th TTIP round, *Borderlex* July 2014.

open trade” although he does not state whether he is referring to trade in health goods or health services or both⁹⁵.

There are both general and specific concerns that have been expressed in relation to the potential opening up of health services to increased market competition. Firstly, in relation to conditions of employment, there is a broadly articulated contention that if the private sector including US providers were to have wider access to health service delivery, then terms and conditions of employment could be affected.

Healthcare is a highly labour intensive activity and one of the largest sectors in the EU. A recent European Commission study reported that in 2010 there were around 17m jobs in the healthcare sector, which represented 8% of all jobs in the then EU-27⁹⁶. Taking just one example in the United Kingdom, it is apparent that the healthcare workforce is increasing both in overall terms and as a percentage of the public sector workforce⁹⁷. In the UK, the public sector health and education workforce now accounts for more than half of state employees, a significant increase over the last decades.

TTIP presents a challenge to this situation if it facilitates greater involvement by private sector healthcare providers, but the potential impact of this on employment, wage and productivity levels is less certain. In other historically traditional areas of public sector employment that have been subject to market-based reform, there is evidence of short, medium and long term changes to employment levels and conditions, although with limited clear trends^{98,99}. A further example is the PIQUE project, which was a broader ranging comparative European study on the impact of privatisation on employment¹⁰⁰. The study found that liberalisation and privatisation of public services have largely negative effects on employment and working conditions and varied effects on productivity and service quality. In addition it found that those positive effects and better performance as compared to other countries were mostly the result of superior regulation, rather than of competition or private corporate initiative.

In addition to the challenges posed to the health workforce by any extension to privatisation that might result from the implementation of the TTIP, additional concern has been voiced in relation to the suitability of private contracting arrangements to health services. The largest range of studies relate to the UK National Health Service with those such as a study undertaken by the Public Services International Research Unit at Greenwich University that found that “Outsourcing of clinical services through ISTCs and GPs ‘out of hours’ services shows some negative effects on patient care, poor value for money as well as evidence of inadequate monitoring and evaluation of the services¹⁰¹. Tim Albrecht’s paper in the European Journal of Public Health on European privatisation of health services concluded that “Universal privatization in

⁹⁵ <http://www.independent.co.uk/news/business/news/ttip-trade-agreement-critics-driven-by-anti-american-sentiment-says-minister-lord-livingston-9705331.html>

⁹⁶ 2012 European Commission Staff Working Document on an Action Plan for the EU Health Workforce

⁹⁷ J. Cribb et al (2014) The public sector workforce: past, present and future IFS Briefing Note BN145

⁹⁸ R. Pedersini (1999) European industrial relations observatory on-line

⁹⁹ Hermann, Jörg Flecker (2009) Privatisation of Public Services and the Impact on Quality, Employment and Productivity (PIQUE) – Final Report

¹⁰⁰ <http://cordis.europa.eu/documents/documentlibrary/122489371EN6.pdf>

¹⁰¹ <http://www.psir.org/reports/broken-promises-impact-outsourcing-nhs-services>

health care challenges the most important principles of socialized health care, while providing insufficient proven ‘benefits’¹⁰².

This in of itself does not provide substantive empirical evidence regarding the privatisation of European health services, nor does it mean that TTIP would necessarily increase the possibility of seeing the widespread privatisation of health services. However, it does as a minimum provide context as to why the issue of sector exclusion for health has been a significant theme within the current discussions.

5.4.3 Sector Exclusions

The first major FTA involving the US was NAFTA. Within this the Canadian Government negotiated a ‘cave out’ for health. What this meant in practice was that Chapter 10 Annex 1001.1b-2: Services Section B of NAFTA excluded Health to the extent that healthcare is a ‘social service’ and it is maintained or provided for a ‘social purpose’. To date it does not appear that NAFTA has resulted in any reduction of the regulatory health policy space, but the wording of the exclusion is considered by commentators to be important as it aligns the exclusion to health remaining a ‘social’ rather than a ‘commercial’ service.

There are different levels of exclusion and it does not appear to be the case that the EU is currently seeking to exempt health in the manner that Canada has from NAFTA. EU negotiators have made a clear commitment that there will be an exemption for public services from TTIP and that this exclusion will include publicly run health services. However, this is a complex area and evidence suggests that the difference between a ‘hard exclusion’ or ‘carve out’ and a soft exclusion’ or ‘voluntary exemption’ will be central to establishing whether and how health services may be impacted by TTIP.

What may be termed a ‘hard exclusion’ or ‘carve out’ of health within TTIP would exclude health services from market access provisions, but would not ring-fence goods such as pharmaceuticals and medical devices. If, however, there is only an ‘soft exclusion’ as is the case with the proposed CETA, then individual Member States would have to make an explicit decision whether to include or exclude their national health services. This links to whether there will be a positive ‘op in’ or negative ‘opt out’ approach within the services chapter of TTIP, although no Member State has to date formally set out its position.

5.4.4 Summary Assessment

The extent to which the market now plays a direct role in health services is evident across the EU, although it would be reasonable to still describe health as being a public service. But what makes a public service public? Funding, regulation, management and delivery all play a part. There is no sense that the funding arrangements for health services would be under any form of threat, nor in theory would the government’s role in health policy and regulation. Yet it is evident that the protection offered to health services in early FTAs such as NAFTA are broader than those being proposed for CETA and TTIP. In addition the environment in Europe is a different one to that in Canada at the time NAFTA was being negotiated in that the boundaries of ‘social’ as

¹⁰² <http://eurpub.oxfordjournals.org/content/19/5/448>



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opposed to 'commercial' continue to blur, which will make the precise wording of any 'hard' or 'soft' exclusion all the more important.

5.5 Investor Protection

Originally, any grievances a foreign investor had with the host state could only be pursued through the domestic courts of that state or through diplomatic espousal¹⁰³. However, with the advent of bilateral investment treaties (BITs) came Investor-State Dispute Settlement (ISDS), deemed by proponents to be a more secure and direct means of investment protection. The first BIT was between West Germany and Pakistan in 1959. This led to the establishment of the International Centre for Settlement of Investment Disputes (ICSID) and United Nations Commission on International Trade Law (UNCITRAL) in 1966. UNCITRAL provides rules of arbitration for ISDS as well as a forum, venue, secretariat and expertise.

5.5.1 ISDS

Under ISDS, foreign investors may bring a damages claim against the host state in an independent tribunal. Typically these treaty commitments include compensation for expropriation, non-discrimination between foreign and domestic investors, free transfer of capital and a guarantee of minimum standards of treatment.

There is no requirement for the investor to exhaust domestic legal proceedings in either country before bringing an ISDS case before an international tribunal. The tribunal is made up of three arbiters, one chosen by the claimant, one by the defender and one chosen mutually. Proceedings are confidential.

A 2014 article written by Corporate Europe highlights that a key question for winning damages involves an assessment as to whether government policies can be construed as “equivalent to expropriation”. The point made is that this argument is made even though the investor’s physical assets are not physically taken¹⁰⁴. The definition of indirect expropriation provides the basis for action against governments on the basis that this could potentially impact on future profits.

As argued in an article in *The Nation* by William Greider, a critic of FTAs, enshrining this doctrine of ‘indirect expropriation’ into trade pacts was part of “a long term strategy, carefully thought out by business” to re-define “public regulation as a government ‘taking’ of private property that requires compensation”¹⁰⁵. The implications, according to Greider, are far-reaching:

"Because any new regulation is bound to have some economic impact on private assets, this doctrine is a formula to shrink the reach of modern government and cripple the regulatory state – undermining long-established protections for social welfare and economic justice, environmental values and

¹⁰³ In this setting, diplomatic espousal refers to the ability of a state to seek damages from the host state on behalf of an aggrieved national at the state-state legal level.

¹⁰⁴ <http://corporateeurope.org/printpdf/1802>

¹⁰⁵ <http://www.thenation.com/article/right-and-us-trade-law-invalidating-20th-century#>

individual rights. Right-wing advocates frankly state that objective – restoring the primacy of property against society’s broader claims.”¹⁰⁶

The selection of arbiters (one by both parties, the third by consensus) appears at first glance to create a neutral panel overall. However, concerns are raised regarding public health cases by the need to obtain a majority decision. There are relatively few arbiters with a public health background.

Furthermore critics argue that arbitrators’ dependence on private appointments may bias them towards the private sector, as allowing through one particular case may open the gates for far more. It was found that 55% of ISDS cases today involved the same 15 lawyers.¹⁰⁷

5.5.2 **History of ISDS**

ISDS was used relatively infrequently until the 1990s, but by 2002 30 cases were being filed a year, and by 2012 more than 60 cases were being filed¹⁰⁸. The turning point came after it was clear that the Uruguay round of GATT did not provide sufficient regulatory environment for investors. ISDS measures were being forwarded in a number of ways. Firstly, ISDS has been embedded in BITs, which began to proliferate in the early 1990s. Such BITs included the Hong Kong-Australia treaty, which subsequently allowed Philip Morris to fight the plain tobacco packaging law in Australia. To date, there are nearly 3,000 BITs in operation.¹⁰⁹ In NAFTA, the first regional FTA to introduce ISDS, which was signed in 1994 the ISDS provision was designed to protect investments against Mexican government seizures of US and Canadian businesses, a risk that has basis in the history of Latin America (evidenced, for example, by the nationalisation of Mexican oil industry in 1938). Finally negotiations on a Multilateral Agreement on Investment (MAI) started in 1995, which attempted to supersede the ‘spaghetti bowl’ of BITs by standardising international investment law and setting ISDS as a standard measure.¹¹⁰

All trade agreements have forms of legal remedy. The most developed is ISDS, but others exist. The EU-Korean FTA has followed the WTO Dispute Settlement Understanding, with provision for ‘proportionate sanctions’. There are other non-binding mediation mechanisms. The US-Korean FTA does have ISDS. The US-Australian FTA does not have ISDS but TPP covering the same states will include it.

5.5.3 **Impact of ISDS**

An in-depth study prepared for the Netherlands Ministry for Foreign Affairs broadly welcomes the inclusion of ISDS in the TTIP agreement and claims that of the 260+ ISDS cases worldwide - “Legislative acts are subject to ISDS procedures only in

¹⁰⁶ Op Cit

¹⁰⁷ <http://www.citizen.org/documents/NAFTA-at-20.pdf>

¹⁰⁸ <http://www.jura.fu-berlin.de/fachbereich/einrichtungen/oeffentliches-recht/lehrende/hindelangs/Studie-fuer-Europaeisches-Parlament/Volume-2-Studies.pdf?1411545557>

¹⁰⁹ http://unctad.org/en/PublicationsLibrary/webdiaepcb2013d9_en.pdf

¹¹⁰ The MAI negotiations were between OECD countries, and its implementation was to have been open to developing countries. Its draft went public in 1997 and, amongst other provisions, proposed restrictions in governments’ ability to limit market access of foreign multinationals. These measures were to be backed up with NAFTA-style ISDS tribunals.

exceptional cases, and these claims are hardly, if ever, successful”¹¹¹. A commonly cited example of ISDS being used to challenge government in the field of health policy was the Dutch firm Achmea who initiated arbitration proceedings against Slovakia over the impending expropriation of private health insurance companies, which linked to the Slovak government’s plans to launch a single state-operated health insurance company. The Dutch company argued that expropriation would not be in the public interest, subject to due process of law, and would be discriminatory. This case was resolved in favour of the Slovakian Government with the Arbitration Court ruling that it had “...no right to interfere with the democratic process of a sovereign state and has no jurisdiction to adjudicate in this matter”¹¹².

Barker, writing for the Atlantic Community, a think tank that receives both US and German state funding, broadly concurs stating that given the relatively short track record by which to judge FTAs, it is difficult to ascertain how ISDS may develop over the next decades. In a briefing for the European Policy Centre Pardo argues that the exclusion of ISDS could have a negative effect on European business, with reduced levels of inward investment¹¹³.

Yet many other stakeholders continue to see significant risk to public services and public policy in ISDS as a dispute resolution mechanism. To highlight just one example Ikenson, in a report for the libertarian Cato Institute, lists “Eight good reasons to drop ISDS from TPP and TTIP”¹¹⁴. Concern is also now being voiced by a number of national governments. Australia has recently renewed its FTA with Japan, which was first arranged 12 years after the end of the Second World War and which still does not include an ISDS¹¹⁵. One of their Senators, under pressure from groups anticipating higher medicine prices, is attempting to introduce a bill banning ISDS clauses from international trade and investment agreements¹¹⁶. The Austrian Federal Chamber of Labour held a panel discussion last March when misgivings re ISDS were expressed. Indonesia is currently cancelling all its FTAs that have ISDS. Of greatest potential impact are current views emanating from the German Government suggesting that they now have serious concerns regarding the inclusion of ISDS in TTIP¹¹⁷.

5.5.4 Health and ISDS

Two central risks to health have been identified. The first is that ISDS could impact within the arena of public procurement and in particular on the ability of governments to bring previously privatised health services back into the state sector. The use of a

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<http://www.google.co.uk/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCMQFjAA&url=http%3A%2F%2Fwww.rijksoverheid.nl%2Fbestanden%2Fdocumenten-en-publicaties%2Frapporten%2F2014%2F06%2F24%2Fthe-impact-of-investor-state-dispute-settlement-isds-in-the-ttip%2Fthe-impact-of-investor-state-dispute-settlement-isds-in-the-ttip.pdf&ei=GXhvVJrGKMflasywgZAE&usg=AFQjCNHifS73ozoVZqoGjG8cirkrk-XK2A&sig2=b2QYPck5ZMi6wh0DyCgvHA&bvm=bv.80185997,d.d2s>

112 http://spectator.sme.sk/articles/view/54060/10/dutch_firm_achmea_loses_arbitration_against_slovak_state.html

113 his view it is possible that omitting ISDS from the TTIP agreement could have a negative impact on European businesses.

114 <http://www.cato.org/publications/free-trade-bulletin/compromise-advance-trade-agenda-purge-negotiations-investor-state>

115 <http://www.smh.com.au/federal-politics/political-opinion/isds-the-trap-the-australiajapan-free-trade-agreement-escaped-20140407-zqrwk.html>

116 <http://www.theguardian.com/world/2014/apr/14/bill-to-ban-investor-state-dispute-settlements-garners-support>

117 <http://www.borderlex.eu/malmstrom-berlin-isds-ceta-ttip-likely-opposed-berlin/>

'ratchet clause' has been cited as a means by which companies currently providing outsourced health services could claim for 'indirect appropriation' of future profits were such services to be terminated or returned to the state sector. This concern over renationalisation has arisen from the cases in Poland and Slovakia where such a situation occurred, both of which are often cited by critical stakeholder groups¹¹⁸. Given that the UK Labour Party for one is currently considering options for the future of the National Health Service and in particular to reverse elements of the country's Health and Social Care Act the potential impact of TTIP will remain a key area of focus.

A second potential risk of ISDS to health relates to ability of governments to regulate in the public interest. (This issue is further discussed in the Chapter on Health Policy Space.)

5.5.5 **TTIP and ISDS**

The inclusion of ISDS is currently the subject of a formal Public Consultation exercise that has been instigated by the European Commission and Member States such as Germany now publically airing doubts about its relevance of such a mechanism for two MDCs with developed national legal systems. Given that the European Commission has yet to publish the results of the formal Public Consultation, it is likely that further pressure will be applied to either removing or fundamentally reassessing the provisions within ISDS.

5.5.6 **Summary Assessment**

An assessment of evidence and opinion pieces suggests the proposed inclusion of ISDS into TTIP as being the single most contentious issue within the current negotiating process. Yet ISDS is already present in a number of existing bilateral agreements, it is used proportionately more by European based companies than those in the US, it does have a limited positive impact on levels of external investment and only a minority of cases are brought by business against government and awarded financial penalties have in most cases been significantly lower than those requested. Yet ratchet clauses have been invoked and there have been notable if limited examples of public health policy being challenged by means of ISDS. It is also apparent that a limited number of Member States are now raising public doubts about its inclusion within TTIP. Whatever the final decision with regard to TTIP this evidence assessment has established that perceived risks to the health policy space have not been fully substantiated. In addition consideration should be given as to whether an ISDS clause in TTIP that has been modified to provide additional safeguards against unwarranted claims by business against government would provide greater or lesser protection than the existing patchwork of BITs.

¹¹⁸ <http://www.tuc.org.uk/international-issues/tuc-submission-european-commissions-consultation-isds>

5.6 Intellectual property

Intellectual property relates to many areas of the proposed TTIP of which pharmaceuticals is from a health perspective of particular importance. The cost to Europe of pharmaceuticals was estimated by the OECD to have been €190bn in 2010, which equates to an average of 1.5% of GDP across European Member States¹¹⁹. The European pharmaceutical industry is also a significant source of investment and employment. The European trade association EFPIA estimates that in 2012 pharmaceutical companies invested an estimated € 30 billion in research and development in Europe and that it directly employs 700,000 people and generates three to four times more employment indirectly¹²⁰.

In relation to IP one pharmaceutical industry position statement has articulated a level of ambition for the TTIP believing it to be:

“A once-in-a-generation opportunity for the EU and US to set aligned high-standards for intellectual property (IP) protection and enforcement. This will contribute to incentivising the development of innovative medicines that meet patients' needs.”¹²¹

Potential intellectual property revision has also been highlighted by a range of stakeholder groups as constituting one of the major risks to European health systems. Reports such as the Commons Network/ Medicines in Europe Forums Position Paper, which presents IP reform to be one of five major risks presented by the TTIP negotiations¹²².

There are important differences between EU and US patentability standards that could impact on how pharmaceuticals are regulated in the EU such differences relate to what prior user rights are based on and how they are defined. There are also differences in how patent applications are handled and patentability determined¹²³.

The first issue to address is Regulatory Data Protection (RDP) and patent protection. It is argued that the need for RDP protection has arisen because the testing required to secure regulatory approvals has become more extensive and expensive¹²⁴. Under European pharmaceutical law innovator pharmaceutical companies are granted a period of regulatory data exclusivity in which a generic applicant cannot refer to the innovator's data to obtain a marketing authorisation. The European legislation was

¹¹⁹ <http://www.oecd-ilibrary.org/sites/9789264183896-en/05/05/index.html?itemId=/content/chapter/9789264183896-55-en>

¹²⁰ http://www.efpia.eu/uploads/Figures_Key_Data_2013.pdf

¹²¹ <http://www.lilly-europe.eu/global/img/PDF/Branch-of-TTIP-position-paper.pdf>

¹²² http://commonsnetwork.eu/wp-content/uploads/2014/03/A-Civil-Society-Response-to-the-Big-pharma-wish-list_Nov2014.pdf

¹²³ <http://www.genengnews.com/insight-and-intelligenceand153/u-s-patent-law-retains-key-differences-with-europe-and-canada/77899549/>

¹²⁴ <http://www.iphandbook.org/handbook/ch04/p10/>

amended in 2004 and currently contains a period of eight plus two (plus one) years of regulatory data protection (RDP)¹²⁵.

Critics believe the extension of RDP on biological medicinal products in the EU to be problematic. In the US protection currently stands at four years with an added eight years for Market Exclusivity. It is argued by some stakeholder groups that the inclusion of terms of 12 years for biologics – as the US has proposed in the TPP - would lock in this term for both the US and the EU, with the concomitant potential to delay the introduction of cheaper generic biosimilars into the European market¹²⁶.

According to an Oxfam study pharmaceutical companies have gradually shifted their business model from focusing on therapeutic innovation towards marketing schemes, and expanding patent protection¹²⁷. A joint position statement from organisations highlights patent linkage as one of the means by which TTIP may seek such patent extensions¹²⁸. Patent linkage refers to the linking of marketing authorisation for a medicine to its patent status. Linkage to patent status is argued to cause delays in generics reaching the market and if TTIP included provisions relating to patent linkage then regulatory authorities would only be able to start the licensing process when the patent is terminated, a situation that is not currently legal in the EU. Critics cite patent linkage as a means to slow the introduction of potentially lower priced generic alternatives¹²⁹.

A recent briefing from the NHS Confederation, an employers stakeholder group suggests that there are additional IP risks within the proposed TTIP.

“The more stringent intellectual property rights in force in the USA could, if extended to the EU, affect the health sector negatively. Extending patent protection to interventions such as diagnostic, therapeutic and surgical procedures could limit and/ or delay patient access to innovative treatments and medicines and to cheaper generic drugs.¹³⁰”

It should be recognised that there is already a high level of alignment between the US and EU such that for instance that Bolar principles¹³¹ apply in broadly similar manner on both sides of the Atlantic, meaning that generics can conclude regulatory requirements prior to the expiry of the originator patent (but not commercialise before then). However it is of note that the European Generics Association in their position paper on TTIP contest that “...we strongly recommend not to attempt creating harmonisation in this area, but to recognise the different approaches between the parties”¹³².

¹²⁵ <http://uk.practicallaw.com/9-518-1152?sd=plc>

¹²⁶ <http://infojustice.org/archives/32502>

¹²⁷ http://www.oxfam.org/sites/www.oxfam.org/files/file_attachments/bp-trading-away-access-medicines-290914-en.pdf

¹²⁸ <http://infojustice.org/archives/32502>

¹²⁹ <http://www.consumersinternational.org/media/1398528/tacd-ip-resolution-on-ipr-in-the-transatlantic-trade-and-investment-partnership.pdf>

¹³⁰ <http://www.nhsconfed.org/~media/Confederation/Files/public%20access/TTIP%20briefing%20-%20final%20pdf%20for%20website.pdf>

¹³¹ http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf

¹³² http://trade.ec.europa.eu/doclib/docs/2013/june/tradoc_151372.pdf

From a research based pharmaceutical industry perspective voices such as Eli Lilly are calling for TTIP to address IP related issues such as to provide for the early resolution of patent disputes before an infringing product is launched on the market, arguing that a lack of predictability over enforcement in Europe is damaging for innovative companies and should be addressed in TTIP.

No estimates of the potential cost impact of pharmaceutical related IP changes in TTIP have been identified during this review. However, critics of CETA such as the Canadian Health Coalition have quoted research study assessments of a potential increase in costs for the Canadian drugs budget that will result from similar IP changes in CETA to be in the region of 15%¹³³. Nonetheless, there are a number of factors that may limit the ability to use such estimates to inform the likely impact of TTIP on pharmaceutical prices in Europe, most important of which are the significantly higher generics costs in Canada by comparison with Europe¹³⁴.

5.6.1 **Summary Assessment**

The interplay between research based and generics pharmaceutical companies based in Europe and those based abroad, makes an overall assessment of IP in relation to pharmaceuticals challenging. Yet the manner in which market and regulatory drivers relating to IP are addressed within TTIP could have a material impact on access to and affordability of medicines in Europe, as well as well as being a determining factor in shaping the future of the European pharmaceutical industry. The enhancement of IP provisions is an area of common agreement between the US and European negotiators, which is likely to provide the pharmaceutical industry with a lever to achieve their goal of strengthening the commitment to IP, which they argue to be necessary for the long term sustainability of the European research based industry. The broader policy debate will focus on the balance between these market needs with regulatory needs. Within this context, the drivers for potential increases in drug prices as a result of TTIP implementation should be carefully assessed as should the potential impact on access to medicines, especially when is it not possible to set these against a value that may or may not accrue from regulatory improvements.

¹³³ <http://openparliament.ca/committees/international-trade/41-2/13/michael-mcbane-1/only/>

¹³⁴ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3999558/>

6.0 Regulatory Cooperation and Reform

One of the fundamental differentiators between the TTIP and other FTAs is the explicit commitment to establish it as a 'living agreement'. This commitment to on-going regulatory reform presents opportunities to improve health related regulation, but it also presents a risk of regulatory dilution.

A primary stated objective of FTAs is reducing regulatory burdens for business, as a central element of providing an enhanced platform for free trade. Yet negotiators have regularly restated the principles underpinning regulatory reform to provide assurances that TTIP will not have a negative impact on population health. The position of EU trade commissioner Karel De Gucht is that EU standards were sacrosanct. He said in the summer of 2014:

“Let me be clear on this very important point: we are not lowering standards in TTIP. Our standards on consumer protection, on the environment, on data protection and on food are not up for negotiation. There is no “give and take” on standards in TTIP.”¹³⁵

The arguments on both sides are not straightforward in that the key to understanding regulatory cooperation lies in the manner in which a small number of words or phrases are interpreted by policy makers and regulators, and how these relate to the arena of health policy and practice.

6.1 Comparative approaches to Regulation

As has previously been discussed there are fundamental differences in the manner in which the US approaches the issue of regulation when compared to the situation in Europe. The most important single distinguisher is that while the US adopts an evidence-based risk assessment approach, Europe adopts a precautionary approach where the starting point is an assessment of potential risk, even where a full evidence base may not be available. Whilst this may at first appear to be a simple matter of looking down the same barrel from different ends, the reality is that it can and does lead to significantly different regulatory outcomes. This issue is discussed further in the section on the precautionary principle.

Firstly, there is the idea of compatibility. The WTO asserts that technical barriers to international trade could be eliminated if Members accept that technical regulations different from their own fulfil the same policy objectives, even if through different means. This approach is based on the European Community's 1985 “new approach” to standardization. Secondly, there is the concept of equivalence in regulatory practice, which presupposes that FTAs such as TTIP do not require participating countries to adopt the same regulatory practices with regulatory convergence focussed on increased mutual recognition of existing practices. However, it would be reasonable to assert that the underlying principle of FTAs is to see regulatory practice simplified. Whilst one can make a connection between simple and less, it would not be reasonable to assume less must automatically mean weaker or poorer regulation. Finally one may consider full-scale harmonisation in the sense of agreeing on the exact same rules is not under consideration for TTIP and it is known from documents

¹³⁵ <http://www.theguardian.com/environment/2014/mar/14/free-trade-deal-eu-us-environment-ngos-sustainability>

released under FOI requests that the European Commission has considered different options such as 'compatibility', 'mutual recognition' and 'equivalence'. Judging from the released documents, 'equivalence' seems to have been the commission's preferred option, meaning that the EU and US would consider their regulations to be of equivalent and thus acceptable standard. This would mean that US firms could follow US regulations when exporting to and investing in Europe.¹³⁶

Once again, there are differences in the US and European approaches to structuring regulatory processes. This is most clearly characterised in the area of food regulation, where the US approach traditionally favours a single point of regulation which could result in a reduction in costs. By contrast, the European approach favours multiple regulatory checks as encapsulated in the concept of 'farm to table' food regulation.

6.1.1 **Precautionary and Risk Approaches**

Central to the idea of regulatory coherence is the establishment of guiding principles that underpin the process of review and change. As has been stated earlier the EU and US come from distinct starting positions, each of which has a historical as well as constitutional basis. These need to be understood alongside the political assessment as to whether FTAs are more free market or social market in orientation.

The social market approach is generally associated with the precautionary principle. The precautionary principle itself has international roots but is very much seen to be a fundamental plank of the European Union and its approach to regulation. The specific term "precautionary principle" originated from Principle 15 of the Rio Declaration on Development and the Environment (part of the United Nations Environment Programme)¹³⁷. Principle 15 would permit a "precautionary approach" when there are threats of "serious or irreversible damage" to the environment. Of particular relevance is that Principle 15 states that a "lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." Equally Article 191 of the Lisbon Treaty states that in relation to EU position on environmental protection "...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"¹³⁸.

The free market approach focuses on an approach built around evidence based risk assessment. Nor can it be assumed that one model is underpinned by a higher level of commitment to protecting human health and well-being than the other, but rather that each is underpinned by a particular approach or methodology. Whilst wishing to avoid over simplification it is apparent that the two approaches generate strong stakeholder responses. This can be highlighted by the CFA report of a 2013 meeting of business representatives in Copenhagen where Shaun Donnelly, a former U.S. trade official now lobbying for the U.S. Council for International Business was heard to remark that "TTIP is only worth doing if the regulatory side is covered, such as getting rid of the precautionary principle."¹³⁹

¹³⁶ <http://www.theguardian.com/environment/2014/mar/14/free-trade-deal-eu-us-environment-ngos-sustainability>

¹³⁷ <http://www.unep.org/Documents.Multilingual/Default.asp?DocumentID=78&ArticleID=1163>

¹³⁸ <http://www.lisbon-treaty.org/wcm/the-lisbon-treaty/treaty-on-the-functioning-of-the-european-union-and-comments/part-3-union-policies-and-internal-actions/title-xx-environment-climate-change/479-article-191.html>

¹³⁹ http://www.centerforfoodsafety.org/files/cfs_trade_matters_76070.pdf

To provide an example of how a risk assessment approach works one may consider the sanitary and phytosanitary chapter within an FTA. This chapter would require a country wishing to bar imports of a hazardous product, to first show by risk assessment that a certain level of harm will occur and cannot be mitigated. For instance, the US took the European Union to the World Trade Organisation court, and won a ruling that the EU had not proved that harm would occur from importing and eating artificial hormone-treated beef from the US¹⁴⁰.

It has been noted that the precautionary principle is often worded differently in different contexts. Yet at the core of each statement is the idea that action should be taken to prevent harm to the environment and human health, even if scientific evidence is inconclusive or incomplete. The European Commission Communication on the Precautionary Principle in 2000 stated that:

"The precautionary principle applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU."

As the principle has been elaborated recently by Nancy Myers implies three additional ideas, beyond "harm" and "scientific uncertainty". In an article for the Environmental Health Network Myers has identified three aspects of the precautionary principle¹⁴¹:

- The notion of seeking alternatives to harmful technologies;
- The idea of shifting to proponents of a technology the responsibility for demonstrating its safety; and
- The goal of transparency and democracy in making decisions about technologies.

As is highlighted in the thematic assessment of TTIP, regulatory coherence appears to be an issue where stakeholders from the United States are putting pressure on negotiators to give ground, with the interpretation of mutual recognition being used to protect and promote the risk assessment approach alongside the principle of needing to be only a single assessment point. On this basis the question is whether there is the willingness, scope and capacity to use the opportunity of TTIP to help improve overall regulatory efficiency and effectiveness is considered further.

Evidence suggests that, in relation to food safety standards, TTIP could see pressures to recognise existing regulatory provisions within each trading bloc. There is evident opposition to approaches such as 'farm to table' that align to the broader precautionary principle underpinning significant elements of European regulation. However in relation to food the precautionary principle appears to cut both ways. One commentator suggests that:

¹⁴⁰ O'Brien, M (2001) Beyond Democratization Of Risk Assessment: An Alternative To Risk Assessment (*Presented to the Society for Risk Analysis, New England Chapter. Boston, MA, December 12, 2001.*)

¹⁴¹ Myers, N (2000) Debating the Precautionary Principle Science and Environmental Health Network

“The US government politicians have criticized the precautionary principle, but many US laws related to occupational and environmental safety embody policies that reflect a precautionary approach, and the US is party to treaties that explicitly call for the precautionary principle.”¹⁴²

This could provide something of a basis to ensure that TTIP works to level up standards. Yet the emerging agenda around unhealthy foods could fall foul not just of provisions within TTIP but also within existing international trade law provided for by the WTO.

6.2 **Summary Assessment**

No current evidence was identified relating to the potential long-term impact of a FTA predicated upon a commitment to ongoing reform. As such it is difficult to make an assessment as to whether the regulatory reform agenda represents a threat or an opportunity to public health. What can be said is that the initial commitment to mutual recognition is likely to be reviewed in the medium to long term and that pressures towards regulatory convergence could well increase. This then raises the issue as to whether convergence will lead to an overall levelling up or down of current standards.

¹⁴² <http://www.consumersinternational.org/media/1402104/tacd-food-resolution-on-the-approach-to-food-and-nutrition-related-issues-in-the-ttip.pdf>

7.0 Heath Policy Space

Health policy space is currently being expanded from an existing policy focus on prevention and harm reduction and regulatory domains such as tobacco control, to include alcohol, unhealthy foods and related lifestyle issues. Coinciding as this does with global trade that is consistently seeking new growth markets, there is evident risk of direct and indirect challenge to the right to regulate. FTAs such as TTIP are likely to form an important element of the legal basis for mediating this increasingly contested space and helping to determine the boundaries of future health policy scope and ambition.

The term ‘health policy space’ refers to the ability of nation states and supra-national governance bodies such as the European Commission to develop policies and practices that improve the health and wellbeing of their citizens. Koivusalo et al define it as:

“...the freedom, scope, and mechanisms that governments have to choose, design, and implement public policies to fulfil their aims.”¹⁴³

The concept was discussed at the 2004 United Nations Conference on Trade and Development (UNCTAD), where the consensus document contended that the increasing interdependence of national economies in a globalizing world and the emergence of rule-based regimes for international economic relations have meant that the space for national economic policy, i.e. the scope for domestic policies, especially in the areas of trade, investment and industrial development, is now often framed by international disciplines, commitments and global market considerations. Koivusalo et al contend that:

“Although the only truly global trade treaty body, the WTO is only one part of a larger international trade regime. Bilateral and regional agreements, often between industrialized and developing countries, are increasing in number and importance, particularly as they generally go beyond requirements within WTO agreements.”¹⁴⁴

The concept of health policy space has been widely discussed. An article by Thow and McGrady highlighted a number of the issues relating to the issue of policy space¹⁴⁵. They assert that:

“Risk management should take place within the framework of existing IIAs, and governments must avoid entering into future investment agreements that overly constrain their regulatory autonomy with respect to public health nutrition.”

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<http://www.globalhealthequity.ca/electronic%20library/Globalization%20and%20Policy%20Space%20for%20Health%20and%20Social%20Determinants%20of%20Health.pdf>

144 op cit p108-109

145 Thow, A.M & McGrady B. Protecting policy space for public health nutrition in an era of international investment agreements Bulletin of the World Health Organization 2014;92:139-145

Koivusalo et al highlight the potential for FTAs or other related agreements to include inadvertent clauses that could later impact on the ability of governments to respond to public health needs¹⁴⁶.

There are two main challenges to health policy space presented by FTAs such as the TTIP. The first of these is direct in terms of potentially prescribing areas of health regulation, and the second is more indirect impacting on the propensity of governments to instigate new public health initiatives.

7.1 **Regulatory Scope**

There is increasing evidence of government seeking to include regulation within the scope of its broader public health policies. This is being observed in the US with the recent attempt to limit sales of carbonated sugar drinks, and in Europe with the introduction in Scotland of minimum alcohol pricing.

The most relevant example relating to public health and alcohol is that of the Scottish government seeking to introduce a minimum price of 50p (€0.63) per unit. The proposal has been forwarded on public health grounds, with evidence provided that demonstrates both a public health need and the potential for the regulatory instrument to positively impact on the problem. The proposed law has faced resistance not just from industry, but also from other European countries and the European Commission, with legal processes currently on-going¹⁴⁷.

By comparison the UK government has recently introduced an ‘alcohol floor price’ which provides a complex mechanism which would impact on an estimated one per cent of sales in the UK¹⁴⁸. The new law has faced challenge from stakeholder groups, which say that it will only lead to a maximum drop in consumption of 0.04%, but it is of interest that the UK Government has made clear that it wished to make a proposal that would address the current legal challenge to the Scottish law¹⁴⁹. There is no current evidence of the UK law being subject to legal challenge.

Whilst the current Scottish example has no immediate link to the current TTIP discussions, it is apparent that if the proposed regulation is already subject to challenge on the basis of European internal market law, it could also be subject to challenge from international trade law and provisions within TTIP. As such what the minimum alcohol pricing example raises is a situation where public health priorities are expanding at the same time that trade law is also expanding creating in its wake further scope for challenge and conflict.

It appears that where public health regulation seeks to extend the bounds beyond the status quo, it becomes at risk of being caught in a complex and multifarious legal web. The issues that need once again to be considered is where the boundaries between trade law and health law should be drawn, what the respective responsibilities of stakeholders should be to ensure that legitimate rights are protected and that agreed means of conflict resolution are provided for.

¹⁴⁶ Loivusalo p 110

¹⁴⁷ <https://www.scotcourts.gov.uk/opinions/2014CSIH38.html>

¹⁴⁸ <http://www.bbc.co.uk/news/uk-26040550>

¹⁴⁹ <http://www.blogs.findlaw.co.uk/solicitor/2014/02/uk-government-sets-floor-price-for-alcohol.html>

7.2 **Regulatory Ambition**

There is evidence that the presence of international trade law can and does have an impact on public authorities seeking to regulate within ‘health policy space’ but the issue under consideration is to differentiate between legitimate input into the policy process and illegitimate input.

7.2.1 **Regulatory Chill**

Regulatory chill has been used as a term for the last decade, most particularly within the area of environmental policy. At its widest it is used to account for any impact that market forces may have on public policy regulators that leads them to refrain from developing, introducing or revising regulatory or other legal measures aimed at enhancing health protection. This may include the actual or perceived threat of ‘capital flight’, but more recently the focus has been on the potential impact of international trade law and specifically FTAs¹⁵⁰.

Philip Morris International (PMI) used TRIPS as part of its legal arsenal against Uruguay’s stricter tobacco packaging rules.¹⁵¹ Claims circulated that Philip Morris was seeking billions of dollars’ worth of compensation, until the company revealed in 2010 that it would seek only \$25m. Although PMI cannot use TRIPS to claim compensation, it forms the background of the case, providing “legitimate expectations” of the regulatory environment.¹⁵²

The current dispute began in the Australian High Court, where British American Tobacco, PMI and the other tobacco companies lost their case of intellectual property infringement. This then led the tobacco industry to look to international trade law with ISDS provisions with the Hong Kong-Australia FTA used to launch an action in 2012. In parallel the tobacco industry has supported countries including Ukraine, Honduras, Indonesia, the Dominican Republic and Cuba to raise the issue with the World Trade Organisation.

Review is ongoing but recent assessment suggests that the application under the ISDS provisions within the Hong Kong-Australia FTA may be dismissed on a technicality¹⁵³. Yet the issue is far from resolution as the issue of ‘treaty shopping’ comes to the fore. So too evidence is being presented on both sides of the argument, aimed at supporting the underpinning case for or against the regulatory measure itself.

The contention here is of attempted regulatory chill, but it is difficult to prove whether this constitutes an attempt to dissuade further action on tobacco control and if it did whether it has in fact led other public authorities away from introducing similar legislation. For instance the Canadian Government stepped back from an initial commitment to introduce plain packaging in 1994, subsequent to threatened action by under the ISDS provision of NAFTA¹⁵⁴.

¹⁵⁰ 2010 Regulatory chill and the threat of arbitration: a view from political science Kyla Tienhaara

¹⁵¹ Alongside a Uruguay-Switzerland Bilateral Investment Treaty.

¹⁵² <http://www.oneillinstitutetradeblog.org/regulatory-chill-25-million-philip-morris-claim-uruguay/>, http://www.smoke-free.ca/eng_home/2010/PMIvsUruguay/Opinion-PMI-Uruguay.pdf

¹⁵³ <http://www.smh.com.au/national/australia-wins-first-battle-in-plain-packaging-trade-dispute-20140702-zst8d.html>

¹⁵⁴

<http://books.google.co.uk/books?id=LJWnHYaflyGc&pg=PA207&lpg=PA207&dq=canadian+plain+packaging+1994&source=bl&>

Tobacco control is an area where BITs and FTAs have been used by industry to challenge the legality as of government initiatives such as plain packaging. ISDS provisions have played a significant role in relation to current legal actions, but they are not the only legal tool that has been called upon.

The tobacco industry has an established history of opposing the introduction of regulatory measures that it believes impacts on its ability to legitimately access markets or which undermines its ability to make benefit from its intellectual property¹⁵⁵. What is evident from past and current legal challenges is that the industry will seek to use multiple channels, often in parallel, with FTAs featuring prominently. The most recent case of this has been between Philip Morris and the Australian government over the introduction of plain packaging for tobacco products in 2011.

The findings in relation to tobacco is that industry will seek to use every available regulatory instrument at its disposal which may result in significant resource implications for governments (the Australian Government has set up both a Tobacco Litigation Task Force in the attorney-general's department and a similar Plain Packaging Task Force) and a consequent increase in regulatory caution within other governments.

Many health campaigners point out the need to treat tobacco as a special case – quoting the problems that Australia and Uruguay have had over packaging disputes, Daniel Huber suggests that “negotiators of the TTP and TTIP must seriously consider the advice of civil society advocates to exempt tobacco from the final agreements”¹⁵⁶.

Whilst the potential for ‘regulatory chill’ is now widely cited to be a risk by civil society groups, there is only limited explicit evidence of public authorities being dissuaded from embarking on a regulatory course as a result of an action or threatened action by an industry or other stakeholder. One recent paper that undertook a more rigorous approach to assessing the impact of BITs on environmental policy, but only found “inconsistent and contradictory results regarding the effect of BITs”¹⁵⁷. The paper does state that “prior to their countries becoming party to additional international investment agreements, policy makers in low, lower-middle, and upper-middle income countries may benefit from more careful consideration of the implications of signing a BIT.”¹⁵⁸ A recent study undertaken by Prof. Dr. Christian Tietje, of the University Halle, Germany and colleagues for the Netherlands Government focused on the particular impact that ISDS provisions could have in generating regulatory chill¹⁵⁹. They post amongst other the often-cited examples of cases taken against the Canadian Government under the

ots=iG1KxPlsri&sig=SgQ4iJ7Bo6jHCQEft-eRMSOPeql&hl=en&sa=X&ei=N250VN2dKM_faq2tgfAD&ved=0CE8Q6AEwBw#v=onepage&q=canadian%20plain%20packaging%201994&f=false

¹⁵⁵ <http://www.ag.gov.au/tobaccoplainpackaging>

¹⁵⁶ http://www.theecologist.org/_tag/6394/0/0/25/trade/

¹⁵⁷ 2013 A BIT OF REGULATORY CHILL? ASSESSING THE EFFECT OF BILATERAL INVESTMENT TREATIES ON THE ENACTMENT OF ENVIRONMENTAL REGULATIONS Shoaf, Jena R.

¹⁵⁸ Op Cit.

¹⁵⁹ The Impact of Investor-State-Dispute Settlement (ISDS) in the Transatlantic Trade and Investment Partnership Study prepared for: Minister for Foreign Trade and Development Cooperation, Ministry of Foreign Affairs, The Netherlands C. Tietje, T. Buatte, J.D. F. Baetens, T., Valkanou., and Ecorys (2014) The Impact of Investor-State-Dispute Settlement (ISDS) in the Transatlantic Trade and Investment Partnership

provisions of NAFTA, but conclude that each case provides “a credible prima facie case for regulatory chill” and that “proving ISDS was the source of the regulatory chill is complex and difficult.” The Tietje study refers to a study published in April 2014 that concluded that the vast majority of investor-state claims arise from executive branch decisions rather than legislative decisions¹⁶⁰.

Regulatory chill has been proposed by a range of stakeholders to be a likely consequence of the introduction of TTIP. The consideration of the evidence provides only limited support for this contention, but makes clear that the current methods to assess ‘regulatory chill’ are in need of further development, and that the concept of regulatory chill itself warrants further refinement. It is also the case that agencies and bodies concerned with the promotion of public health should, where permitted, engage with the development process associated with FTAs and assess prospective interventions in order to consider their compatibility with relevant provisions in international trade law. When considered as a whole, it is evident that establishing evidence of unwarranted regulatory caution is problematic. Establishing a causal link between such regulatory caution and the actions of litigant under a FTA or even the simple presence of an FTA has not fully been established.

7.2.2 **Regulatory Snare**

A second impact of legal action taken against governments under international law can be termed ‘regulatory snare’. This is a further aspect of the ‘regulatory chill’ hypothesis that focuses on the impact on governments that become involved in legal challenge to regulation brought about under international law.

The regulatory snare aspect of this case has two elements. Firstly, there is the physical legal process, which can stop the implementation of a policy. This is the current situation in relation to minimum alcohol pricing in Scotland. The second aspect of regulatory snare is the impact on public authorities and other stakeholder groups, with respect to the resource and cost impact of having to deal with often protracted legal proceedings.

The concept of regulatory snare has been developed as part of this review process. Whilst it is evidently the case that governments can and do find themselves preoccupied with regulatory issues and facing significant costs and administrative commitment, it is important to add a further level of consideration as to whether such an impact can be considered to be unreasonable or even if it can be considered to constitute in and of itself a means to inappropriately impact upon government, rather than it simply being a by-product of the process of law making. Such an assessment will require further consideration and research.

7.2.3 **Summary Assessment**

It is clear that industry has demonstrated that it will seek to challenge public health related regulation and that international trade law provides a range of platforms to facilitate such a challenge. Whilst WTO legislation continues to be used it is FTAs and most particularly the ISDS provisions within BITs such as TTIP that are most regularly accessed in order to take cases forward.

¹⁶⁰ J. Caddel and N. Jensen (2014)

However, whilst the evidence review has identified attempts by industry to challenge proposed new public health regulation, elements of which could be deemed to be at the boundaries of legitimacy, few recent examples have been found of such attempts being successful in dissuading governments from their chosen regulatory path.

Stakeholder groups continue to view TTIP as providing an enhanced platform to challenge the right to regulate. Yet an examination of the evidence brings into question the extent to which ISDS within TTIP would represent a fundamental change in the international legal framework and whether a negotiated 'ISDS' could in fact provide an improved framework to that offered by the ISDS provisions within the existing patchwork of BITs affecting European Member States.

ISDS provisions within TTIP now appear likely to face removal or modification, but even if this does prove to be the case public health policy and regulation will continue to face legal challenge through the existing legal framework.

8.0 Governance and Accountability

The TTIP negotiating process is more open than for prior FTAs, partly by design and partly as a response to growing stakeholder and public comment. TTIP additionally includes a more developed governance structure than is usual for FTAs, reflecting the commitment of the negotiating partners to the establishment of a 'living agreement'.

8.1 Overview of TTIP Governance

Government and business have historically led FTAs, with civil society and other stakeholders making the majority of representations outside the formal decision making structures. Assessment of the governance structures of NAFTA is that the establishment of a Free Trade Commission and Secretariat have been of limited impact¹⁶¹.

TTIP partially aligns to this pattern in that the majority of the negotiating process has taken place exclusively on a state-to-state basis, although TTIP involves more structured and ad hoc consultation with stakeholder organisations and the wider public than has historically been the case with other FTA negotiating processes. The two distinguishing elements are:

- Structured Engagement - TTIP has a built in thematic governance structure that will continue in existence after ratification with an on-going remit to support further regulatory cooperation; and
- Ad Hoc Engagement - TTIP has seen additional formal consultation exercises undertaken in relation to the potential impact on SMEs and to gather views on the inclusion of ISDS as the arbitration mechanism within the Investment Chapter.

Whilst discussions on TTIP remain guarded it is apparent that there are provisions to set up internal regulatory governance structures. Firstly there is the TTIP Oversight Body, to which a series of sub-committees would report. The Transatlantic Regulatory Cooperation Council (TRCC) would bring together representatives of regulatory agencies in the EU and US to monitor the implementation of commitments made under TTIP and consider new priorities for regulatory cooperation including joint development of future regulations. The relationship of TRCC to government and broader democratic structures is yet to be fully set out.

In addition there are likely to be Joint Management Committees to discuss concerns about particularly themes such as SPS. However, the review found little information about how this committee would function and how it would relate to the ISDS mechanism.

8.2 Civil Society Engagement

Despite there being limited structured opportunities for the formal engagement of civil society groups, TTIP has seen a high level of civil society engagement on both sides of

¹⁶¹ <http://www.internationaldemocracywatch.org/index.php/north-american-free-trade-agreement>

the Atlantic. There is a TTIP Advisory Group for invited stakeholder organisations and there have additionally been a number of consultation events set up in both Europe and the United States at which members of the respective negotiating teams have been present.

The engagement of civil society in the TTIP process has been growing in recent months, with the first formal public demonstration against TTIP being held in the UK in July 2014. Individual campaign groups such as Stop TTIP have sought to challenge both individual chapters within TTIP but also the fundamental commitment to a new US EU free trade agreement in the form presented. A further development has been an attempt to initiate a Citizen Initiative to challenge both CETA and TTIP. Evidence suggests that the campaign was close to achieving the required one million signatories required to invoke action, but in September 2014 was deemed by the Commission to be outside the bounds of the process¹⁶².

8.3 Public Opinion

The state of public opinion across Europe to TTIP is not easy to assess, although there is evidence to suggest broad but limited support for TTIP that is offset by concerns being expressed in relation to particular issues such as health and arbitration systems.

Whilst no comprehensive public opinion survey has been undertaken to date in Europe or the US concerning TTIP there are a number of interesting studies to consider. Firstly, there has been a study for the Atlantic Council and the Bertelsmann Foundation who are both explicitly in favour of TTIP. This study surveyed more than 300 respondents from business, academia, government, legislatures and the media via an electronic survey, with participants selected on the basis of their expertise in trade policy and familiarity with the issues at hand in the negotiations. Respondents came from both the US and Europe, with stakeholders from Washington, Brussels and Germany heavily represented¹⁶³. The survey suggested broad ranging support for TTIP, with limited comment made on specific provisions. Further trade specific surveys have been undertaken such as that by in Belgium for the American Chamber of Commerce in Belgium, which is again supportive of TTIP.¹⁶⁴

Another study on TTIP this time undertaken by Pew Research, an independent US based think tank, demonstrated that a small majority of US and German voters support the overall idea of a transatlantic FTA. However, the survey findings also suggest that there is a more critical view, particularly amongst German respondents to specific provisions including governance and transparency as well as issues such as food standards¹⁶⁵. Overall the team behind the study believes that TTIP is suffering from a "double deficit" in the form of a lack of understanding combined with a lack of trust.

Finally, a UK study commissioned by the Trade Union UNITE focused on the potential impact of TTIP on the National Health Service. This poll of more than 2,600 voters across 13 marginal Conservative-held seats, found 68% opposed the inclusion of the NHS as part of the deal. Opposition was highest among those planning on voting for

¹⁶² <http://www.theguardian.com/politics/2014/aug/21/wheres-outrage-transatlantic-trade-investment-partnership>

¹⁶³ http://www.bfna.org/sites/default/files/publications/2014%20TTIP%20Stakeholder%20Survey_web.pdf

¹⁶⁴ <https://www.surveymonkey.com/s/2K2YQQ3>

¹⁶⁵ <http://www.pewglobal.org/2014/04/09/support-in-principle-for-u-s-eu-trade-pact/>

Labour (78%) or the United Kingdom Independence Party (77%), but even among Conservative supporters only 23% backed the inclusion of the NHS in TTIP¹⁶⁶.

The Pew study also raised the issue as to whether the European Commission should be leading European negotiations, with a majority of German respondents believing not and arguing for a repatriation of powers to Berlin.

8.4 **Summary Assessment**

The TTIP negotiating team followed an established route in providing only limited transparency, which has led with a widely held belief that a 'legitimacy gap' has rapidly developed. Current public consultations on issues such as ISDS are unlikely to assuage a range of critical stakeholder groups and there is increasing evidence of discontent bleeding into national political debate.

The broader political debate appears to currently be more balanced with centre-left and centre-right governments and opposition parties broadly supporting TTIP. Only more leftist and green parties are siding with civil society in complete or partial opposition to TTIP, alongside a number of far right parties such as Liga Norda in Italy and Vlaams Belang in Belgium. Given the apparent delay to the original timetable that would have seen TTIP concluded by the end of 2014, this could change most particularly if public opinion turns more explicitly against TTIP.

The most recent admission by European Commission representatives that the process needs to be opened up could be seen as a valuable concession or as being too little too late. The European Ombudsman is currently undertaking a public consultation in relation to transparency and public participation in TTIP, as part of one of two own-initiative inquiries launched on July 29 against the Council and Commission¹⁶⁷. The original timescales for TTIP envisaged conclusion in 2014 but with the timescales now extended into 2015 pressure continues to grow for a more open and inclusive policy development and implementation process. The argument in support of significantly greater levels of transparency and involvement are underpinned not only by the immediate ambition of TTIP and its focus on non-tariff based reform, but as importantly on the commitment to TTIP being a 'living agreement'.

¹⁶⁶ <http://www.theguardian.com/society/2014/aug/07/voters-want-nhs-exempt-us-trade-pact-ttip-eu-privatisation>

¹⁶⁷ <http://ttip2014.eu/blog-detail/blog/Public%20consultation%20Ombudsman%20TTIP.html>

9.0 Study Recommendations

Neither trade compliant public health nor healthy trade agreements provide any guarantee of achieving a balance between trade and health. Yet it is evident that the potential for international trade and health law to conflict is growing and as such there is a clear need for increased dialogue and engagement.

Whilst it must be noted that there remains a significant resource imbalance between industry interests by comparison with public health groups, it is also evident that a dialogue has been started as part of the TTIP process that there would be value in developing. Evidence would suggest that the issue could be addressed in the following manner.

9.1 Healthy trade agreements

The public health community can contribute to the design of ‘healthy trade agreements’ by ensuring that health considerations are fully taken into account at the development stage. This would involve enabling provisions to support regulation for public health and ensuring that adverse consequences associated with other chapters and provisions are avoided or mitigated.

These kinds of negotiations require lawyers, health policy officials and trade officials who are all experts in their own fields and fully conversant with the other disciplines. Such collaboration also requires a government mandate as well as the creation of institutional mechanisms for ongoing cooperation. An additional challenge is that the negotiations themselves have been undertaken behind closed doors with only limited scope for constructive engagement.

For TTIP to have the potential to be a ‘healthy trade agreement’ there is a need to establish a meaningful platform for engagement between relevant stakeholder groups and a governance structure that can consider how best to reconcile areas of difference. Ultimately this must be a democratic process as it involves decisions regarding policy priorities and long-term goals. Such a process must also recognise the need for investment and support so as to ensure that issues of resource asymmetry are addressed and critical voices are given support to ensure that both current and future dialogue is made credible and meaningful.

There is a need to establish how FTAs such as TTIP can be seen to align to the development of global health policy and programmes. The WHO has developed a strategic framework around health systems, which they define as “all the organizations, institutions, resources and people whose primary purpose is to improve health¹⁶⁸”. Consideration should be given as to how these global structures can be used to connect to the development of regional trade policies such as TTIP.

¹⁶⁸ <http://www.who.int/healthsystems/about/en/>

9.2 Trade compliant public health

In developing public health strategies that seek to utilise pricing or other regulatory levers, it appears to make sense for health policy officials to work closely with trade officials to ensure that flexibilities can be built into trade law and fully utilised. For example, if there are ways of regulating access to unhealthy foods, alcohol and tobacco in a manner that is consistent with the broader objectives of TTIP, then it makes sense to explore these.

Certain principles need to be followed to ensure that a policy is compliant with existing national, European and international law. Free trade agreements add a further level to this process, yet many of the basic provisions will be common. There is a particular challenge in that the European Union has limited competency within the health arena. That having been said it has established infection control function in ECDC and public health is also relatively well established. On this basis it would make sense to seek to future proof initiatives such as TTIP by developing potential scenarios that could see for example how increased consumption of unhealthy products may be manifested and consider how various public policy interventions that could help address associated problems.

This approach focuses on public health agencies proactively assessing how different interventions could be impacted by provisions in international trade agreements such as TTIP and seeking to adopt interventions that have the lowest chance of coming into conflict. The recent decision by the UK government of a 'minimum floor pricing' for alcohol is an example of such a potentially trade compliant policy. The extent to which this can be considered a 'win win' will be dependent on how effective such measures are in achieving their stated public health objectives.

9.3 Summary Assessment

The purpose of this report has been to objectively assess existing evidence on the potential impact of TTIP on the health of Europe's 500 million citizens. Very limited evidence was found of direct potential health benefits, whilst the indirect effect of any broader economic growth that may result from TTIP are likely to be highly dependent on how any increase in GDP is deployed, and more particularly on how it can help to foster innovation in health goods and services.

By comparison the risks from TTIP do carry with them the potential to reduce health outcomes and negatively impact on the ability of government to regulate for public health improvement. Yet in most cases the proposed provisions within TTIP are likely to compound rather than create problems and the policy development process has started a dialogue with regards to how best to marry trade and health goals.