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Developing a True Transatlantic Partnership

—a High Standard Trade Agreement
to Propel the Global Economy

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1. EXECUTIVE SUMMARY

THE BACKDROP

- 1.1 Global growth has been stalling for several years, with measures of industrial output falling since before the 2008 financial crisis. Deep trade liberalisation can be a catalyst to economic growth again, such as through a UK-US free trade agreement ("FTA"). Such an agreement has been mooted since the early 1990s. There is a Trans-Atlantic Trade and Investment Partnership ("TTIP") between the US and the EU currently under negotiation (although not actively at present), which the UK would no longer be a part of once it leaves the EU. Without the restrictions associated with EU membership, the UK has an opportunity to negotiate a deep and effective trade agreement with the US, including in areas that previously have been too politically difficult for negotiation.
- 1.2 The UK and the US already have relatively free trade in terms of market access for goods, with relatively low levels of tariffs generally. However, the terms of an agreement could go further and seek to reduce non-tariff barriers and address behind the border barriers and regulatory distortions (which we have classified as anti-competitive market distortions ("ACMDs")), which would promote greater economic growth.
- 1.3 Such an agreement will have a number of challenges. UK consumers have already professed concerns about lower regulatory standards in agricultural products and privatisation of the National Health Service ("NHS") under an UK-US FTA, and the UK will have to manage such interest groups carefully. The US administration and president on the other hand, have expressed a mercantilist approach to trade, accompanied by "Buy American" rhetoric. Further, in previous negotiations, such as in TTIP, the US has shown an unwillingness to negotiate on certain areas that would be priorities for the UK, such as financial services. While such matters present challenges, a shared commitment to open trade and removal of distortions to drive competitive markets will be a strong starting point for negotiations. Negotiations on a free trade agreement can begin immediately as a matter of law ; there are no impediments from Article 50 as long as the UK is following the principle of sincere cooperation with the EU. UK ministers should start engaging with US counterparts immediately to discuss the opportunities for collaboration, and prioritising areas for negotiation and agreement.

A UK-US AGREEMENT CAN ACHIEVE MORE BARRIER REDUCTION THAN TTIP

- 1.4 **Regulatory promulgation.** In a UK-US agreement, there is an opportunity for both parties to agree regulatory promulgation mechanisms, which ensure that new regulations are pro-competitive. This should move away from the precautionary principle adopted by the EU, which, when applied, requires

1. Shanker A. Singham, *Freeing the Global Market: How to Boost the Economy by Curbing Regulatory Distortions* <http://www.cfr.org/world/freeing-global-market-boost-economy-curbing-regulatory-distortions/p29123>

2. Nothing in Article 3(1) of the Treaty for the Functioning of the European Union or Article 50 of the Treaty on European Union ("TEU") prevent a member state in the process of exiting the EU from engaging in trade negotiations with third countries as long as no legal commitment enters into force prior to the exit and the duty of sincere cooperation under Article 4 TEU is respected.

the producer / importer to prove absence of danger. As part of this process, the US and the UK could undertake joint analysis of current domestic markets to review and remove existing barriers to trade and investment. This could work in parallel to the review by US federal agencies of regulations for repeal, replacement or modification required under the recent executive order signed by President Trump.

- 1.5 **Food and Agriculture.** As part of any negotiation, the US will inevitably seek greater openness on agricultural products. The UK will have to commit this to an extent and should seek greater commitments in other areas, particularly services, in return. The US has also expressed concerns with the so-called Meursing table, which is the EU's special tariff rate for imported products containing milk protein, milk fat, starch and sugar content. The UK could offer to reform or eliminate this. The US, on the other hand, has domestic distortions through subsidies and similar programmes, alongside tariffs, that the UK would seek to address in an FTA.
- 1.6 **Regulatory barriers.** There needs to be agreement on labelling standards, noting that in many areas, the EU, and therefore current UK, standards exceed those of the Codex Alimentarius General Standards, e.g. in fishing and aquaculture, as well as agreement on use of geographical indications. The most difficult area will be agreement on application of standards. The agreement should specify use of appropriate, proportionate standards for agricultural products, based on sound scientific evidence, and remove unnecessary Sanitary and Phytosanitary ("SPS") and Technical Barriers to Trade ("TBT") measures, and agree on eligibility, authorisation and assessment processes. This in particular can be politically challenging, and the UK will have to manage concerns from interest groups.
- 1.7 **Government Procurement.** The US has barriers in government procurement, through the Buy American Act ("BAA"), which applies to federal government procurement of supplies and construction materials. This has recently been reinforced through President Trump's "Buy American, Hire American" executive order which requires a review of current compliance and use of waivers. This will make an agreement in this area potentially challenging, and the UK will potentially have to seek special arrangements in relation to government procurement.
- 1.8 **Financial Services.** The UK and the US are relatively open on financial services in terms of market access. Greater regulatory co-ordination and recognition of home state regulation could deliver significant gains to both parties. In the TTIP negotiations the US expressed an unwillingness to include regulatory co-ordination in financial services in trade negotiations and so this may be an area of difficulty. However, the US has, for example, previously signed a mutual recognition agreement with Australian regulators in 2008 for mutual recognition in certain areas of financial services and deferred compliance measures are in place with the EU, so there is precedent for such an approach.

- 1.9 **Standards.** Standard setting currently is very different between the UK and the US, and was a major stumbling block in the TTIP negotiations, but this is largely because of the EU process. The challenge here will be for the UK to develop a new conformity assessment system for standards that can support the creation of mutual recognition agreements in new trading arrangements, including with the US and the EU. This could be the development of a private-led ecosystem with lighter state oversight, starting with mutual recognition agreements across different sectors that had been initially discussed between the US and the EU, including information technology, telecommunications products attached to public networks, medical devices, electrical safety, electromagnetic interference, pharmaceuticals, amongst others.
- 1.10 **Other Areas.** There are several other areas where the UK and US have common goals and will have to work to align regulations going forward, which for the UK, will potentially mean a move away from current EU rules. For example, both the UK and the US are committed to strong intellectual property protection, but would have to address areas such as use of geographical indications. There are public concerns about an agreement with the US leading to the privatisation of the NHS. It is unlikely that large or significant parts of the NHS would be opened up to provision by foreign companies. Where there is private provision, US providers have already invested in the area, and there is scope for the US to invest in the private healthcare market. However, the substantial barriers posed by the socialised healthcare system are unlikely to change, and the UK could easily reserve this area in services negotiations.

UK-US FTA AS PART OF A WIDER UK TRADE POLICY

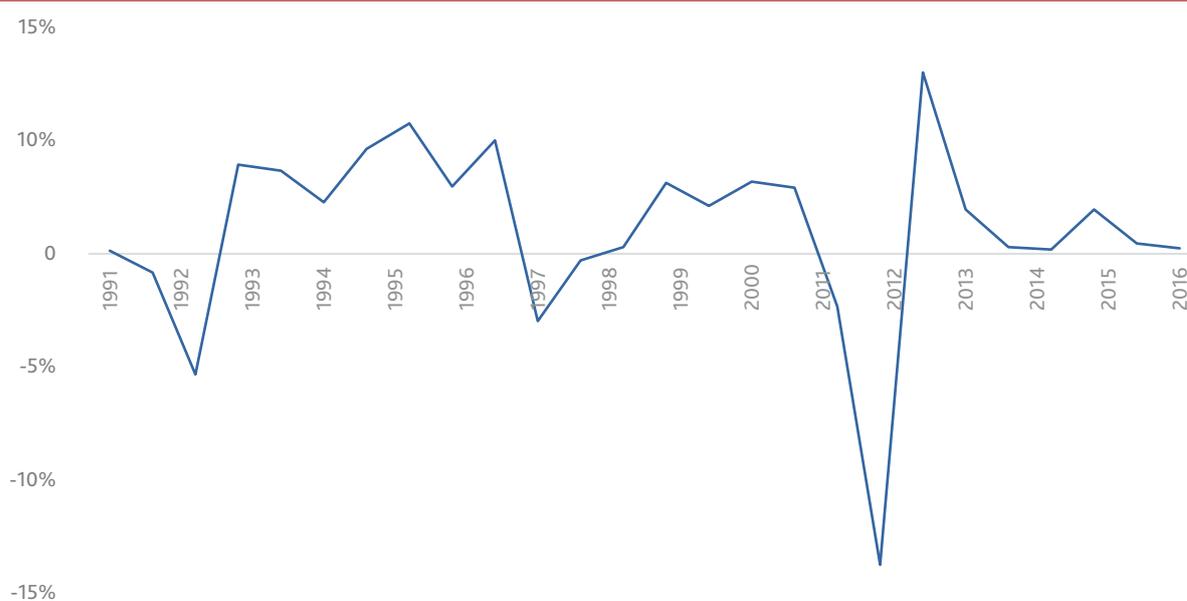
- 1.11 The concurrent negotiations with the US and the EU will present both opportunities and challenges. The UK sits between the US and the EU in many areas of law and regulation, and concurrent negotiations mean that the UK can act as a bridge in certain key areas. The challenges are primarily in areas where the EU and US regulate in very different ways, and it may not be possible in certain cases to have an agreement that works for both parties and enables a single supply chain across the US-UK-EU region. In financial services, for example, to ensure that the UK can continue to transact business in the EU without being locally licensed and supervised, there will have to be some mutual recognition and ongoing co-ordination of regulation, especially prudential regulation. The question is whether this can also be extended to include the US and other countries. The key will be to agree arrangements that are enabled by MRAs across the UK, US and EU while the parties are also working to ensure global standards develop in a more consumer welfare-enhancing direction.
- 1.12 This agreement can be a stepping-stone to working with other like-minded countries to make progress on ACMDs and behind-the-border barriers. We have separately proposed a “Prosperity Zone”, a plurilateral agreement amongst countries with similar goals of open trade, competition on the merits as an organising principle, and property rights protection. This could be a starting point to addressing the global economic growth challenges.
- 1.13 The UK-US FTA is also important because it will ensure that the UK does not become by default “locked in” to EU standards and product regulation such that it cannot be flexible in negotiating FTAs with other countries.

2. THE ECONOMIC CONTEXT FOR BREXIT

Below: Figure 1: Index of Industrial Production —Advanced Economies (growth rate)

Source: IMF (2017)

- 2.1 The global economy has been stalled for over a decade. Growth in measures of economic output and wealth creation such as industrial output has fallen significantly since before the global financial crisis. As illustrated below, there was relatively strong growth in the IMF's index of industrial production for advanced economies in the mid-late 1990s. Output fell with the 2001 recession, following which there was more subdued rates of growth. This has worsened since the financial crisis, with little to no growth in industrial output in recent years. In the five years preceding the crisis, the average annual growth rate for advanced economies in the IMF's index of industrial production was 2.4%, compared to an average annual growth rate of 0.9% after 2010.³
- 2.2 In GDP terms, the OECD noted in 2016⁴ that growth was flat in advanced economies and slowing in emerging economies that had been the 'global locomotive' since the global financial crisis. Secretary General Angel Gurría called for "comprehensive policy action...to ensure that we get off this disappointing growth path and propel our economies to levels that will safeguard living standards for all".



3. IMF (2017), "Prices, Production, Labor and Population", available at <http://data.imf.org/?sk=6AC22EA7-E792-4687-B7F8-C2DF114D9FDC&slid=1439776194766>, accessed on 30 March 2017.

4. OECD Global Interim Economic Outlook, March 2017 <http://www.oecd.org/economy/economicoutlook.htm>

- 2.3 While the reasons for this slump are myriad, it is notable in this context that with the exception of the recently concluded trade facilitation agreement, no multilateral trade agreement round has been concluded for twenty-two years, a longer period than at any other time in the history of the World Trade Organization ("WTO") or its predecessor, the General Agreement on Tariffs and Trade ("GATT"). Indeed, an argument can be made that the consensus in support of deeper trade liberalisation was in deep trouble as early as prior to the 1999 WTO Seattle meeting protests.
- 2.4 The early and enduring success of the GATT means that tariffs have come down but behind the border barriers and anti-competitive market distortions ("ACMDs") have become the major obstacles to free trade and competitive markets, pre-requisites for economic growth. ACMDs can only be dealt with through deeper, more liberalizing agreements among nations, either at a multilateral or regional/bilateral level. These ACMDs particularly affect services exports, which are disproportionately affected by regulatory barriers. We argue that addressing these matters will be key to the success of policies that seek to promote growth and wealth creation.
- 2.5 What are the blockages in the trade agenda? The attempt to deepen trade liberalisation through the so-called Singapore Issues failed in the late 1990s, and the attempt to launch a new trade round in 1999 met with disaster in Seattle when the US raised the issue of trade sanctions for labour violations, a position which was anathema for developing countries. An argument can certainly be made that the only reason the Doha Round was launched was because the launch meeting in Doha, Qatar followed the terrorist attacks on September 11th, 2001. Little progress was made and it is widely (though not universally) considered that the Doha Development Agenda ("DDA") was effectively killed off at the Nairobi Ministerial Conference in December 2015 and the WTO needs to move on. Worse, the DDA distracted WTO members from developing the built-in agenda on services towards deeper liberalisation.
- 2.6 Other agreements which were attempts to introduce more trade liberalising measures, such as the Trans-Pacific Partnership ("TPP") and Trans-Atlantic Trade and Investment Partnership ("TTIP") have proved impossible either to progress, or to ultimately ratify, whether due to adverse domestic politics or substantive negotiation differences. Protectionist and populist impulses have made traditional trade liberalisation very difficult to accomplish.
- 2.7 There is a need for a deeply liberalising agreement between countries that agree on the fundamental pre-requisites for a growing economy. There are very few such countries in the world, but we have suggested in our paper *Trade Tools for the 21st Century*⁵ which countries are broadly in this category.⁶ Of these countries the US has made it clear that it wishes to have a trade agreement with the UK, and the purpose of this paper is to evaluate what that deal might look like and what benefits it might confer on people in both countries.
- 2.8 A trade agreement between the UK and the US has been mooted for a considerable period,⁷ but has not been possible because of the UK's membership of the EU which has precluded it from negotiating an agreement with another customs territory. Now that the UK is about to leave the EU, trade agreements with other countries are possible. The UK is able to do a considerable amount of preparation prior to actually leaving the EU. This work can and should begin in earnest for a deal with the US.

5. <http://www.li.com/activities/publications/trade-tools-for-the-21st-century>

6. They are US, Australia, Canada, Singapore, New Zealand, and possibly Switzerland.

7. See for example calls in 2000 by Senator Phil Gramm for the UK to join NAFTA <http://www.economist.com/node/302480>

- 2.9 Negotiating a deal with the US at the same time that the deal is being negotiated with the EU will present both opportunities and challenges. A UK-US trade agreement could be a comprehensive agreement, committing the parties to high standards of openness and competition, which makes progress on behind the border barriers which particularly afflict UK and US service providers and spur the progress on these matters more widely.
- 2.10 This can be accomplished by:
- 2.10.1 greater border measure reduction;
 - 2.10.2 improving competitive markets by eliminating ACMDs; and
 - 2.10.3 improving property rights protection.
- 2.11 This paper aims to address how the US and the UK should seek to reduce behind the border barriers and domestic anti-competitive market distortions generally, followed by brief analysis of existing barriers in the US and UK markets and how such barriers might be reduced or removed entirely in a free trade agreement between the two parties, focusing in particular on the structural matters of product standards and mutual recognition. Finally, we consider how this process between the UK and the US fits into both sides' wider trade policy and political considerations—in the case of the US, NAFTA and the Trump administration's trade policy goals, and in the case of the UK, establishing an independent trade policy, including a deep and special trade relationship with the EU (we have described a four-pillar approach to building the UK's trade policy in our paper "A Blueprint for UK Trade Policy").⁸
- 2.12 A non-exhaustive list of examples of the existing UK/EU and US barriers is contained in Appendix 1.

8. <https://lif.blob.core.windows.net/lif/docs/default-source/default-library/170427-final-trade-blueprintweb.pdf?sfvrsn=0>

3. UK AND US TRADE RELATIONSHIPS

- 3.1 The US and UK have historically enjoyed close economic and diplomatic relations. These ties were strengthened during the First and Second World Wars and the post-war period. The relationship goes beyond economics and politics. They are ties of shared values, shared culture and a commitment to free trade, free markets, competition as an organising principle for the economy, and free and open liberal democracy. No matter who the leaders of the UK and US are, these ideas are so embedded that they cannot easily be removed.
- 3.2 Today, the US is Britain's largest single export market, and its second-largest import supplier (behind Germany).⁹ The US is also the single largest source of, and destination for, foreign direct investment for Britain.¹⁰ Both countries were founding entities in the GATT system itself which did more to reduce border barriers than any other single venture.
- 3.3 Since the 1980s, the special relationship between the UK and US has incorporated a desire to have closer economic ties between the two countries. The UK acceded to the European Economic Community in 1973, at some considerable cost to the Commonwealth countries, and the preferences that they had enjoyed. As part of the European customs union, the UK has not been able to consider even the most basic agreement with the US to reduce border barriers except through the EU. That said, as noted above, many US members of Congress have called for a UK-US agreement of some sort. Some have called for the UK to accede to NAFTA, some for a bilateral agreement (even though the UK cannot enter one, or accede to any other agreement as long as it is part of the customs union).
- 3.4 A Transatlantic Free Trade Area or Agreement ("TAFTA") has been floated since the early 1990s by proponents of free trade on both sides of the Atlantic. TTIP is the current proposed US-EU trade deal. The High Level Group on Jobs and Growth formally recommended that the US begin negotiations with the EU in February 2013.¹¹ The Council of the European Union issued Directives for the Negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America in June 2013; negotiations were formally commenced in July 2013.¹² After fifteen rounds of negotiation (from July 2014 to October 2016), talks have stalled. The US and EU have been unable to come to agreement on any of the 27 proposed chapters. Agriculture, standards, regulatory coherence and public procurement are areas of particular difficulty. If TTIP is revived,¹³ the same issues that prevented progress will still be present.
- 3.5 There have been objections to the TTIP in the EU. Sigmar Gabriel, German Minister for Economic Affairs and Vice Chancellor, gave an interview in late August 2016 in which he proclaimed the TTIP negotiations to be "de facto failed", adding that "nothing is moving" because the "Europeans did not want to subject ourselves to American demands".¹⁴ His comments came

9. <https://www.ons.gov.uk/economy/nationalaccounts/balanceofpayments/articles/ktradeandinvestmentrelationshipwiththeunitedstatesofamerica/2016>

10. <https://www.ons.gov.uk/economy/nationalaccounts/balanceofpayments/articles/theuktradeandinvestmentrelationshipwiththeunitedstatesofamerica/2016>

11. http://trade.ec.europa.eu/doclib/docs/2013/february/tradoc_150519.pdf

12. <http://data.consilium.europa.eu/doc/document/ST-11103-2013-DCL-1/en/pdf>

13. See Paul Ryan's speech on 19 April 2017 as recited at <https://www.theguardian.com/us-news/2017/apr/19/paul-ryan-london-visit-us-uk-trade-agreement-brexite>

14. <http://www.dw.com/en/germanys-vice-chancellor-gabriel-us-eu-trade-talks-have-failed/a-19509401>

on the heels of a series of large protests in Germany against TTIP, and the Comprehensive Economic and Trade Agreement (“CETA”) with Canada. On the American side, Senate Leader Mitch McConnell (R-Ky.) and other prominent Republicans have criticised European treatment of agriculture. It is thought that one major advantage of a US-UK FTA would likely be more relaxed dynamics on the regulation and trade of agricultural products.¹⁵

- 3.6 Key House and Senate Republicans, as well as President Trump, have indicated that they support and expect a forthcoming free trade agreement between the UK and US. Then-candidate Trump said on the 24th of June 2016 that Britain “will always be at the front of the line”, in reference to President Obama’s warning that a post-Brexit Britain would be “at the back of the queue” for future US trade deals.¹⁶ The political climate in Washington is such that President Obama’s opposition to Brexit and a subsequent US-UK trade deal is likely to generate support for such a deal amongst congressional Republicans at least through the end of the 115th Congress. Senators Cotton (R-Al.), Isakson (R-Ga.), Hatch (R-Ut.), Corker (R-Tn.), and Lee (R-Ut.) have all publicly expressed support for a US-UK FTA; Senators Cruz (R-Tx.), Lee (R-Ut.) and Sessions (R-Al., US Attorney General) issued a letter of condemnation to President Obama before the UK Brexit referendum vote for interfering in British sovereignty.^{17,18}
- 3.7 President Trump has delivered top line messages on trade that are hostile to countries that distort their markets in anti-competitive ways. For example, he is highly critical of China’s domestic practices which distort markets and artificially lower the cost of certain Chinese producers in markets around the world. He rightly identifies that global trade rules have not done a good enough job of penalising these distortions. Trump’s America First rhetoric is an attack on trade policies he finds unfair to American businesses, and American workers. This is not especially unlike the policies adopted by other American presidents even if the rhetoric is more strident. He has also vowed to punish those companies who choose to move jobs outside of the United States; in one high-profile case, he convinced Indiana-based Carrier to keep 800 jobs in the US, rather than moving them to Mexico. However, on trade measures one can start to see the beginnings of how President Trump’s high level messages will be interpreted by a Republican House of Representatives and Senate. In the case of the border tax proposal, one of the reasons that large US exporters support the Ryan proposal is that many countries impose a value added tax (“VAT”) on imports, whereas the US does not (although the US does impose varying state-local sales taxes). Hence US exporters face a cost increase in external markets which their competitors do not face in the US. In this context the VAT which can be quite high (20% and above in many EU member states, as high as 27%, in Hungary for example) represents a significant distortion. As we have discussed in our approach to ACMDs and potential policy responses, a border tax may be a way of correcting this distortion.¹⁹
- 3.8 President Trump has initiated renegotiation of NAFTA.²⁰ Such a re-negotiation could incorporate elements of an anti-distortion model (like the Prosperity Zone described below). This would deliver solutions satisfactory to US, Canadian, and Mexican consumers, businesses, and workers. A simple imposition of tariffs on all goods coming from Mexico (including from American companies with production bases in Mexico) would be highly distortive and unproductive, and

15. <http://www.politico.com/tipsheets/morning-trade/2016/02/major-tpp-political-players-talking-warren-hits-tpp-ahead-of-signing-spring-showers-bring-ttip-flowers-212510>

16. See Paul Ryan’s speech on 19 April 2017 as recited at <https://www.theguardian.com/us-news/2017/apr/19/paul-ryan-london-visit-us-uk-trade-agreement-brexit>

17. <http://www.politico.eu/article/the-bright-side-of-brexit-us-uk-bilateral-bliss/>

18. http://www.cruz.senate.gov/files/documents/Letters/20160620_BrexitLetter.pdf

19. <http://www.li.com/activities/publications/trade-tools-for-the-21st-century>

20. <http://www.nbcnews.com/news/us-news/white-house-trump-says-u-s-will-not-withdraw-nafta-n751731>

likely lead to the loss of American jobs, but measures to deal properly with distortions would have an entirely different effect.

- 3.9 President Trump has talked publicly about a free trade agreement with the UK, and has shown an aversion to multilateral and regional agreements. This is based on a concern that these agreements are based on a lowest common denominator, and are with countries with considerably different labour and environmental standards. However, it is feasible that an agreement with a like-minded group of countries would be met with support by the Trump administration. Initially any US agreement will likely be on a bilateral basis with other countries, and the UK will be no exemption. However, the ultimate destination of the agreement could still be a broader, platform agreement such as the Prosperity Zone set out below.

4. HOW CAN THE US AND THE UK MAKE PROGRESS ON BEHIND THE BORDER BARRIERS AND ACMDs?

- 4.1 Progress can be made on behind-the-border-barriers and ACMDs by gathering like-minded countries who believe in competition on the merits as an organising economic principle.
- 4.2 Ensuring that those countries that believe in these concepts come together to pursue these ends would be a positive step forwards. We believe these like-minded countries can come together to form a prosperity zone (the "Prosperity Zone"). The concept of a Prosperity Zone was first floated during Gov. Mitt Romney's 2008 presidential campaign.²¹ The Prosperity Zone recognises that the nations of the world are not all equally committed to open trade, competition on the merits as an organising principle, and property rights protection. The ultimate goal of the Prosperity Zone is to effect a global reduction in ACMDs. As described in *Trade Tools for the 21st Century*, ACMDs exist to
- "limit the number and range of competitors; to restrict the ability of individual companies to compete by artificially increasing their costs or artificially lowering competitors' costs; and to favour state-owned enterprises",
- and are proliferated through the use of:
- "exclusive distribution rights, licencing regimes, corrupt public procurement practices, geographical/labour limitations, scientifically unsound standard-setting, limitations on direct-to-consumer advertising, forced production shifting, exemptions from onerous regulations for 'favoured' corporations, and outright subsidies".²²
- 4.3 While the GATT has successfully eliminated many at-the-border tariff barriers, many behind-the-border barriers still exist as ACMDs. The examples of ACMDs listed above are often the most difficult areas to negotiate in trade negotiations. The General Agreement on Trade in Services ("GATS") agenda initiated after the Uruguay Round in 1994 has not materially progressed barriers in services trade, as was one of the goals of the so-called Built-In Agenda. The services offers made by countries as part of the Built-in Agenda are very weak and minimally cover the sectors. Only one sector has been properly dealt with—telecommunications, through the GATS Telecommunications Annex and the related Reference Paper on Competition Safeguards. After the 1997 Annex on Telecommunications, the members intended that financial services and other sectors would follow.
- 4.4 We have previously laid out in *Trade Tools for the 21st Century* the gains which would be achievable under a full reduction of tariff and non-tariff barriers in a Prosperity Zone which included the UK, US, Switzerland, Canada, Hong Kong SAR, Singapore, New Zealand and Australia. Our calculations showed that roughly 2-3% year-on-year growth in gross world product ("GWP") would be possible under this framework. These gains are based on our

21. Referred to as the Reagan Economic Zone <http://www.politifact.com/truth-o-meter/statements/2012/may/17/mitt-romney/mitt-romney-once-distanced-himself-ronald-reagan-n/>

22. <https://lif.blob.core.windows.net/lif/docs/default-source/publications/trade-tools-for-the-21st-century-pdf.pdf?sfvrsn=4>

methodology for measuring ACMDs.²³ We assume that the Prosperity Zone leads to a 30% reduction in ACMDs over a fifteen-year period in these countries.

- 4.5 As the US, Canada and Switzerland retain significant agricultural distortions, it would be best to begin negotiations with those countries who carry the least defensive baggage in agriculture: the UK (subject to jettisoning the Common Agricultural Policy ("CAP")), Australia, New Zealand and Singapore. As the TPP has been abandoned by the US, these nations will be eager to re-engage in a more promising round of negotiations. Once the Prosperity Zone had been ratified by those four nations, the process to accede the US, Canada, and perhaps Switzerland, could begin, with an eye to the further accession of several like-minded Pacific Alliance countries, including Chile, Colombia, Peru and Mexico. Another relatively expeditious action would be the UK acceding to and then building on the P-4 agreement. In this case, Chile would already be a member (along with New Zealand, Singapore and Brunei) and accessions of the Pacific Alliance countries would be possible.
- 4.6 A bilateral UK-US agreement should be deeply liberalising and a stepping-stone to a Prosperity Zone. As soon as possible, the UK should agree a memorandum of understanding with the US regarding intent to sign a high-standards free trade agreement after the UK has formally exited the European Union. Discussions in relation to this FTA could begin immediately; there is no legal reason to wait for the Article 50 process to be concluded before commencing negotiations.²⁴ The issue is more of a political matter. The US will have to determine whether it is worthwhile negotiating towards an agreement with the UK, based on how much they believe that the UK will emerge at the end of the Article 50 process (i.e. by April 1, 2019) fully outside of the Customs Union and no longer a member of the EEA (which at the time of writing is the stated expectation of both the British government and the EU institutions). In this case, the UK will simply be a third country negotiating an FTA with the EU as is the case for many countries that it is negotiating FTAs with.

²³ See Shanker A Singham and Molly Kiniry *Introduction to Anti-Competitive Market Distortions and the Distortions Index* (September 2016)

²⁴ As acknowledged in paragraph V of the Council of the European Union's European Council (Art. 50) guidelines following the United Kingdom's notification under Article 50 TEU issued on 29 April 2017 and see also Francis Hoar, *The United Kingdom's Right to Negotiate Free Trade Agreements before leaving the European Union* <http://www.lawyersforbritain.org/files/uk-right-to-negotiate-free-trade-agreements-before-leaving-eu.pdf>

5. SCOPING AN FTA BETWEEN THE US AND UK

- 5.1 In general terms, except in agriculture, tariffs between the US and UK are low. The major impediments are in the regulatory and behind the border areas. It is here where a US-UK agreement can be most effective.
- 5.2 Appendix 1 contains an inventory of barriers in both the US and UK which each party's businesses face in the other's market. Trade in services faces barriers on both sides of the Atlantic and regulatory differences cause significant costs and distortions in goods and services trade. More particularly, the US barriers of most interest are in the following broad categories:
- Agricultural subsidisation
 - 'Buy America' and public/defence procurement
 - Financial services
- 5.3 The major UK barriers are broadly in the following categories
- Food standards and SPS
 - Product standards and regulation
 - Data protection
- 5.4 We have set out below an analysis of these barriers and how they could begin to be addressed within the scope of an FTA between the UK and the US.

6. IMPROVING REGULATORY PROMULGATION TO DELIVER CONSUMER WELFARE

- 6.1 While an agreement on tariffs in industrial goods between the US and UK should be relatively straightforward, there will be more issues in the regulatory area. The UK is currently bound by EU regulation. As this will be the starting point post-Brexit (because the Great Repeal Bill will transpose substantially all of EU regulation into UK law),²⁵ any discussion of a regulatory agreement between the US and the UK must start with EU regulation. The regulatory promulgation in the EU includes the precautionary principle. Although not formally defined and used in the Treaty for the Functioning of the European Union (“TFEU”) only in the context of environmental regulation, the precautionary principle is an important influence on the regulations in the EU through case law and practice. As noted in a Commission Communication in 2000,²⁶ it may be invoked “when a phenomenon, product or process may have a dangerous effect, identified by a scientific and objective evaluation, if this evaluation does not allow the risk to be determined with sufficient certainty”, and while it is not to be extended generally to all products and processes placed on the market, where action is taken under the precautionary principle (which will be determined by authorities on a risk basis), a producer or importer may be required to prove absence of danger. The principle is applied to not just environment (as provided in the TFEU), but to conservation policy, food legislation and human, animal and plant health. While the precautionary principle is recognised in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (“SPS Agreement”), the approach in the EU goes far beyond what is required and recognised under the WTO.
- 6.2 The precautionary principle is not widely deployed in regulatory promulgation in the US and this is part of the reason for wide regulation divergence between the UK/EU and the US. The guidance given to US regulatory authorities in Circular A-4 from the Office of Management and Budget²⁷ states that cost-benefit analysis is a primary tool for regulatory analysis and states a number of considerations and presumptions that should form part of such analysis. It specifically counsels against “conservative assumptions and defaults (whether motivated by science policy or precautionary instincts) [which] will be incompatible with benefit analysis as they will result in benefit estimates that exceed the expected value”. This is in line with the SPS Agreement, which states that any sanitary and phytosanitary (“SPS”) measures implemented must be based on a risk assessment. Where there is no sufficient scientific evidence available, only provisional measures are permitted, accompanied by an obligation to seek to obtain additional information necessary for a risk assessment, and to review the provisional measure within a reasonable period of time.²⁸
- 6.3 In the US-UK agreement, there is an opportunity for both parties to agree a regulatory promulgation mechanism that ensures that new regulations are pro-competitive by setting up a system that builds on the process outlined in Circular A-4 and the UK’s domestic equivalent

25. The United Kingdom’s exit from and new partnership with the European Union White Paper <https://www.gov.uk/government/publications/the-united-kingdoms-exit-from-and-new-partnership-with-the-european-union-white-paper>

26. Commission Communication (COM (2000)1)

27. <https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/omb/circulars/a004/a-4.pdf>

28. https://www.foodwatch.org/fileadmin/Themen/TTIP_Freihandel/Dokumente/2016-06-21_foodwatch-study_precautionary-principle.pdf

cost benefit analysis process undertaken in carrying out impact assessment of legislation, set out in the Green Book, and moves away from the precautionary principle where appropriate. The UK Competition and Markets Authority (“CMA”) is already in the forefront of doing market studies that look at regulations that have anti-competitive effects, but we would argue that on both sides of the Atlantic many of these reports and analysis do not go far enough in terms of specific analysis of regulations and their consumer welfare effects. For example, the CMA’s analysis of the banking sector in the UK does recognise that capital adequacy rules can have negative competitive effects, it also says that these are prudential matters related to the sectoral regulator which the competition agency should not deal with. These sectoral studies can be converted into specific regulatory analyses. The problem is not that regulations are too many or even that costs of compliance for businesses are too great, but rather that their effect is anti-competitive, and this depends on the nature of specific regulations.

- 6.4 New Zealand and Australia have historically collaborated together via a productivity commission to analyse their existing domestic markets with the ultimate aim of proposing recommendations for a package of measures to enhance cooperation between Australia and New Zealand in relation to their competition and consumer protection regimes.²⁹ A similar joint analysis conducted by the UK and the US could lead to the removal of existing barriers and obstacles to trade and investment. On 24 February 2017, President Trump signed an executive order³⁰ that requires federal agencies to designate a Regulatory Reform Officer and set up a Regulatory Reform Task Force to improve implementation of regulatory reform initiatives and identify regulations for repeal, replacement or modification that impact on jobs, are outdated, unnecessary or ineffective, impose costs greater than benefits. This could be done in collaboration with the UK’s Regulatory Policy Committee’s work in this field.³¹

29. *Australian and New Zealand Competition and Consumer Protection Regimes*, Productivity Commission Research Report (December 2016)

30. <https://www.whitehouse.gov/the-press-office/2017/02/24/presidential-executive-order-enforcing-regulatory-reform-agenda>

31. <https://www.gov.uk/government/organisations/regulatory-policy-committee>

7. FOOD AND AGRICULTURE

TARIFFS AND QUOTAS

- 7.1 To the extent that part of what the US will need is access to the UK's agriculture market, the UK will have to be committed to more open trade in agricultural products. There are many products that the UK does not produce, or produce products that are directly competitive or substitutable with them. In these cases, the UK could simply reduce or eliminate its tariffs and quotas unilaterally. To do so would not affect UK farming interests but would immediately serve to lower any food price inflation that affects the UK on exit from the EU, and send a strong message to trading partners that the UK is serious in its commitment to becoming a leader in the global trade agenda. Some examples of such products which the UK does not produce are set out in section 7.4.
- 7.2 The US has also expressed its concern with the so-called Meursing table, which is the EU's special tariff rate for imported products containing milk protein, milk fat, starch and sugar content. The UK could offer to eliminate the Meursing Table in total and simply categorise products, rather than their recipes.
- 7.3 There are also many distortions in the US agriculture sector, through subsidies and similar programmes, and the US operates TRQs on 44 lines of agricultural products, that could usefully be addressed in a US/UK FTA.
- 7.4 The UK can lower agricultural tariffs on a number of products without affecting domestic producers for example:
 - 7.4.1 **Rice:** The UK does not produce rice but does have processing facilities. It is therefore very much in the UK's interest to lower or eliminate the rice tariff. The US has previously requested that the EU lower its tariffs on brown rice in the TTIP agreement. This is something the UK could offer immediately.
 - 7.4.2 **Peaches, Citrus Fruits and Olives:** The US has complained about EU hidden subsidies for these industries. The UK can eliminate any TRQs for all these products, as well as remove any provision for payments to producers of these products (which are not produced in the UK).
- 7.5 The US operates TRQs in 44 lines of agricultural products including products that the UK produces such as dairy, beef and animal feed, which the UK would wish to have reduced or eliminated entirely for UK exports to the US. The UK would likely seek to follow the NAFTA model for its agricultural products, which provided for duty-free and unlimited access for beef amongst US, Canada and Mexico.³²

³² <https://www.fas.usda.gov/data/review-us-tariff-rate-quotas-beef-imports>

- 7.6 The US also subsidises agricultural production extensively, distorting the market in favour of domestic producers and certain crops. For example, the US provides a Federal Crop Insurance program to American farmers, which has been criticised for encouraging farmers to gamble on risky plantings and marginal acres at a significant cost to the US government and taxpayers. American farmers receive a financial incentive to buy the insurance coverage from existing insurers, with the US government ultimately covering any losses incurred in excess of predetermined limits under the insurance policy. Farm subsidies are also accused of being the reason behind high consumer pricing for agricultural products, due to there being a lack of incentive for farmers to price products competitively.³³

ENSURING TECHNICAL REGULATION AND LABELLING IS NOT A BAR TO TRADE

- 7.7 There is a range of technical barriers to trade where progress can be made if the UK is out of the EU. We have set out some of them in the following sections.
- 7.8 There are many areas of food labelling where EU standards exceed those of the Codex Alimentarius General Standards (for example in fisheries labelling and aquaculture). As the EU and the US legislation relating to mandatory food labelling are both based on international Codex standards, they share similarities. The EU and the US both require detailed labelling on food packaging, to communicate to the customer key facts about the product, including nutritional and allergen information. However, there are some differences between the two regimes, for example (i) how nutrition information is communicated (in the US calories must be stated by reference to servings; in the EU all nutrition listings must be displayed per 100g but may also be given per portion;³⁴ and (ii) the US lists sodium content (measured in milligrams) on nutrition labels, while the EU lists salt content (measured in grams).³⁵
- 7.9 The US will also likely seek to challenge the European Geographical Indications, including the expansion of country of origin standards to place of farming. The Codex does not require place of origin designation. Traditional terms that are restricted such as tawny, ruby and chateau which the Codex also does not include are problematic. The World Wine Trade Group, consisting of Australia, Canada, Chile, Georgia, New Zealand, South Africa, and the US have campaigned on various aspects of wine designation and will be anxious to secure more openness from the UK than from Europe.³⁶
- 7.10 The US-UK agreement can be used to agree appropriate, proportionate standards for such agricultural products, based on sound scientific evidence. In addition, the agreement should seek to eliminate unnecessary SPS measures and import controls that act as barriers to trade, where there is no proven risk to human, animal or plant health. It should be noted that this discussion might not be straightforward, as there is likely to be some resistance from producers and consumer groups in the UK, particularly with regard to hormone-treated beef products.

33. https://www.researchgate.net/publication/264887771_Farm_Subsidies_and_Obesity_in_the_United_States

34. See The Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act (US) and Regulation (EU) No 1169/2011 Food information to consumers (EU) Regulation (EU) 1169/2011

36. <http://www.wwtg-gmcv.org/p/achievements.html>

- 7.11 There are a number of EU bans in the area of TBT/SPS measures. These include bans on growth hormones in beef and beta agonists. In particular, there is an EU ban on ractopamine which promotes leanness in meat. Codex has suggested that ractopamine at specific residual levels (10 parts per billion (ppb) in comparison to limits set by the US Food and Drug Administration at 30 ppb for beef and 50 ppb for pork) has no effect on human health.³⁷ The WTO has already found the EU ban in violation of WTO rules. As a result of the ongoing dispute, grain-fed, High Quality Beef (“HQB”) was allowed a special TRQ. Since other countries complained about this, the quota was opened up to Argentina, Australia, Canada, New Zealand and Uruguay, and the US now controls only 45% of the HQB quota. The beneficiaries of the HQB quota will likely seek to replicate the quota in its entirety for the UK market but the UK and US can look at it in a more holistic way if the UK signals more general openness with respect to US meat imports under an FTA.
- 7.12 The EU has rules against food products as a result of animal cloning. Such food products are categorised as “novel foods” under EU law, and require authorisation from the Commission to be placed on the EU market.³⁸ The Commission released guidelines to state that novel food will only be approved for use in the EU if they do not present a risk to public health, are not nutritionally disadvantageous when replacing a similar food and are not misleading to the consumer. They must undergo a scientific assessment prior to authorisation to ensure their safety.³⁹ Similarly, authorisation must be obtained for use of genetically modified organisms (“GMO”) in cultivation and the marketing of food and feed and derived products. All applications for GMO authorisation must be submitted with a dossier with experimental data and a risk assessment. In March 2015, the EU allowed member states to ban GMO for non-science based reasons, a clear WTO violation, and pathogen reduction treatments. In the last case, the purpose of these anti-microbial washes is to kill pathogens and make the products safer for human consumption. There is no evidence of a danger to human health—indeed not using effective disinfectants presents a danger to human health.
- 7.13 EU certification requirements limit US agricultural exports such as meat, dairy, and eggs. In general, health certificates are required for all products of animal origin imported in the EU and phytosanitary certificates are needed for all plant products that could introduce pests into the EU. Import requirements for animals and animal products are harmonised across the EU in a three-part process. First, the EU must recognise a country as eligible to export a particular animal or animal products. In the absence of an approved US residue plan for horsemeat, the US has effectively been restricted from exporting horsemeat to the EU since 2011. Secondly, the EU requires lists of approved establishments based on submissions from US government agencies. Only those products processed at approved establishments may enter the EU. In the US, such establishments include the Food Safety and Inspection Service, the Animal and Plant Health Inspection Service, the Food and Drug Administration, and the Agricultural Marketing Service. Lastly, animal or public health certificates based on the model certificates published by the EU and signed by US officials must accompany all imports.⁴⁰
- 7.14 Under the European Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (“REACH”), manufacturers and users of chemicals,

37. <http://www.foodsafetynews.com/2012/07/codex-votes-69-67-to-advance-ractopamine-limits-for-beef-and-pork/#.WNut5o-cE2w>

38. <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2283&from=EN> Regulation (EU) 2015/2283 of 25 November 2015 on novel foods

39. http://europa.eu/rapid/press-release_MEMO-15-5875_en.htm

40. https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20and%20Agricultural%20Import%20Regulations%20and%20Standards%20-%20Certification_Brussels%20USEU_EU-28_2-13-2017.pdf



such as pesticides, must prove they are safe before they are released into the EU market. Of particular interest, endocrine disruptors are considered of similar regulatory concern as substances of very high concern under REACH. However, endocrine disruptors are difficult to distinguish from endocrine active substances (substances that can interact or interfere with normal hormonal action, but without adverse effects). The Commission is currently working with Member States, the European Chemicals Agency and the European Food Safety Authority to produce full guidance to identify substances with endocrine-disrupting properties in pesticides and biocides, to be opened to public consultation in Summer 2017.⁴¹

- 7.15 Milk is barred if the somatic cell count ("SCC") (white blood cells) is above 750,000 ml even though this has no effect on the actual milk quality or its capacity to harm humans. In comparison, the EU SCC requirement is 400,000 cells per ml. Since milk and dairy products for export can't be easily segregated, many farms in the US have been forced to meet the 400,000 EU standard.⁴²

Above: Parade of prize-winning cattle at the Royal Cornwall Show. Wadebridge, June 2016.

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Shutterstock.com

41. <https://echa.europa.eu/-/endocrine-disruptors-efsa-and-echa-outline-guidance-plans>

42. <http://www.progressivedairy.com/news/industry-news/scc-limit-in-the-us-remains-at-750000>

- 7.16 The EU's citrus canker rules keep citrus from Florida out of the territory of the EU, because it states that where there is one infected plant, produce from the whole grove is banned.
- 7.17 There are also bans at the member state level (such as the French ban on bisphenol A). The US would want all of these issues to be corrected but to the extent they are member state issues that do not apply in the UK, this is an advantage to the UK.
- 7.18 With regard to Animal Welfare Certificates, the EU's process is in excess of what is required in SPS certification procedures from the Codes, OIE and the International Plant Protection Convention.
- 7.19 The US imposes certain SPS measures and import controls on certain meat products and eggs, which the UK is likely to seek to have eliminated for imports from the UK. In 1997 the US closed its market to a number of EU animals and animal products (including beef and goats) on the basis that such products posed a risk of carrying bovine spongiform encephalopathy ("BSE"). In March 2014, the US aligned its import requirements to that of the World Organisation for Animal Health ("OIE"), through introduction of the 'comprehensive rule'. The OIE standards call for countries to base their trade policies on the actual risk of cattle and cattle products harbouring BSE. In light of this, the comprehensive rule incorporates a risk-based approach aligned to international animal health guidelines and scientific understanding, and in particular permit the export of all boneless beef to the US, regardless of the risk category of the country of origin.⁴³
- 7.20 However, before trade is able to resume between the EU and the US, EU establishments must be approved and member states re-instated by the Food Safety and Inspection Service ("FSIS"), which the Commission describes as an "ongoing" process.⁴⁴ In order to be certified for FSIS equivalence, it must be determined that the member state has maintained an equivalent beef slaughter and/or processing system (to include providing supporting documentation of appropriate government oversight and an onsite audit).⁴⁵ The UK is in the process of applying for equivalence for meat products, and is currently at 'stage 2' of the process, which involves submission of a self-reporting tool and supporting documentation.⁴⁶
- 7.21 The most recent export eligibility list published by the United States Department of Agriculture provides that the UK is only eligible to export pork to the US. Exports of beef and veal are conditional on the UK obtaining verification of FSIS equivalence. The UK will want to obtain a similar eligibility standard to that of Canada, which is considered eligible to export beef and veal, lamb and mutton, goat, pork, poultry and ratites and egg products freely to the US.
- 7.22 The US also requires that formal authorisation and pest risk assessment must be carried out for all food crops, including edible fruit and vegetables before it is permitted for import. For those products that are not approved pending risk assessment, authorisation can take several years to be granted.⁴⁷ Assessment is carried out by the Animal and Plant Health Inspection Service under the umbrella of the US Department of Agriculture. The UK is likely to seek recognition of its food crops under the FTA to avoid the assessment and authorisation process entirely, or at a minimum, seek to agree that UK applications will be expedited beyond the existing timeframes.

43. http://www.aphis.usda.gov/publications/animal_health/2013/faq_bse_rule_final.pdf

44. http://madb.europa.eu/madb/sps_barriers_details.htm?isSps=true&barrier_id=10784

45. https://www.fsis.usda.gov/wps/wcm/connect/4872809d-90c6-4fa6-a2a8-baa77f48e9af/Countries_Products_Eligible_for_Export.pdf?MOD=AJPERES

46. <https://www.fsis.usda.gov/wps/wcm/connect/2514b05f-82b2-4c1a-a7f2-fdf4610d4d8e/Equivalence-Status-Chart.pdf?MOD=AJPERES>

47. http://madb.europa.eu/madb/sps_barriers_details.htm?isSps=true&barrier_id=10783

8. IMPROVING ACCESS TO GOVERNMENT BUSINESS OPPORTUNITIES

- 8.1 Various laws enacted by the United States Congress require that the federal government favour US suppliers in making purchases. These laws are rather complex in their application and are subject to a variety of exceptions. 'Buy American' provisions are a condition of US federal government grants to state, municipal or other organisations, including transit authorities. Current federal policy, enunciated by President Trump, directs US Government agencies to seek to favour domestic suppliers to the full extent allowed by law.⁴⁸
- 8.2 The core US statute in this regard is the Buy American Act of 1933 ("BAA"), which has been amended over time. The BAA applies to procurement of supplies and construction materials by the US Government. (Thus, for example, if the US government issues a solicitation for construction of an infrastructure project, the BAA would apply to the procurement).
- 8.3 Concerns about controlling the cost of federal procurements lie at the heart of BAA exceptions. For instance, the BAA requirement to purchase US-made steel may be waived by the government if the domestic cost is 25% or more expensive than if foreign-sourced, if the product is not available domestically in sufficient quantity or quality, or "if doing so is in the public interest," an inherently malleable term that has been invoked on many occasions to allow the substitution of foreign for domestic supplies.
- 8.4 Agency-specific regulations govern the extent of BAA preferences. The US Department of Transportation ("DOT") requires that, to justify turning to foreign sources, the cost of the American component must be so high as to increase an entire project's contract cost by 25%, not just the cost of the specific item. Regulations applicable to non-DOT purchases, however, require adding a 6% cost differential in comparing bids, "[u]nless the head of the agency specifies a higher percentage".
- 8.5 The Trade Agreements Act of 1979 gives the President certain latitude to waive Buy American provisions. Moreover, under this Act, imports from "designated countries" (including most notably nations with which the U.S. has free trade agreements such as Canada, Mexico, Australia, and New Zealand) generally are not subject to BAA restrictions.
- 8.6 The American Recovery and Reinvestment Act of 2009 ("Recovery Act") expanded Buy American preferences by including strict domestic requirements for iron, steel, and manufactured goods for contracts for public buildings and public works awarded by federal agencies using stimulus funds available pursuant to the Recovery Act. The Recovery Act included an exemption for projects valued at \$7,804,000 or more with respect to products from specified countries that have entered into free trade agreements with the United States. The Recovery Act repeated the earlier requirement for the US Commerce Department to grant waivers with respect to covered

48. Presidential Executive Order on Buy American and Hire American signed on 18 April 2017 <https://www.whitehouse.gov/the-press-office/2017/04/18/presidential-executive-order-buy-american-and-hire-american>

products (1) that are not produced in the U.S. in sufficient and reasonably available quantities, or (2) where domestic purchases would raise the overall project cost by over 25%, or (3) where application of the Recovery Act's preference "would be inconsistent with the public interest."

- 8.7 The Recovery Act was shortly followed by guidance from the Office of Management and Budget ("OMB") as to how the Buy American restrictions should be implemented, which ultimately resulted in a reduction in the use of waivers post-2009 as they became harder to justify. For example, the waiver relating to unreasonable cost was only available if a domestic purchase would raise the cost of the *entire project* (not just the item in question) by 25%, which would be relatively rare. In addition, if a product met the availability and cost criteria, it would be unlikely that an agency could put forward a compelling public interest exemption to satisfy the waiver provisions. The OMB guidelines also included a requirement on any agency granting a waiver to publish a detailed written justification in the Federal Register.
- 8.8 On 18 April, President Trump signed a new 'Buy American, Hire American' executive order⁴⁹ that sets the policy of the executive branch to maximise the use of domestically produced goods, and to rigorously enforce and administer immigration laws, with development of reforms to the H-1B skilled worker visa program to counter fraud and abuse of the program. The executive order requires agencies to monitor, enforce and comply with Buy American laws, and minimise the use of waivers, with an assessment of current compliance and development of policy proposals to maximise procurement of domestically produced goods. The executive order also requires that before granting a public interest waiver, the relevant agency will have to take appropriate account of whether a significant proportion of the cost advantage of a foreign-sourced product is the result of use of dumped steel, iron or manufactured goods, or the use of injuriously subsidised steel, iron or manufactured goods. Further, the Secretary of Commerce and the USTR will also have to assess the impacts of all US FTAs, including the WTO Agreement on Government Procurement, on the operation of Buy American laws and implementation of domestic procurement preferences. The executive order states that "it shall be the policy of the executive branch to maximise, consistent with law, through terms and conditions of Federal financial assistance awards and Federal procurements, the use of goods, products, and materials produced in the United States." The order cautions that it "shall be implemented consistent with applicable law", which means that it does not expand the scope of Buy American preferences beyond the ambit of what the existing Buy American statutes provide. It remains to be seen whether the Trump administration's direction of travel is to extend the restrictions which the Obama administration implemented, or whether they may be reined in.
- 8.9 This executive order may make an agreement on government procurement more difficult. The requirement for consideration of distortions before the application of the public interest waiver is consistent with our proposals on addressing ACMDs. However, the executive order also potentially creates uncertainty with the review of FTAs, and the outcomes of this would provide useful guidance on implications for a US-UK agreement. The UK should try and negotiate a special arrangement with relation to government procurement.

49. <https://www.whitehouse.gov/the-press-office/2017/04/18/presidential-executive-order-buy-american-and-hire-american>



- 8.10 Finally, several US states have introduced “Buy America” proposals with the intention of limiting state contracts to companies that manufacture products made with a certain percentage of domestic content, sometimes as high as 100%. Various municipalities have sought to adopt similar restrictive procurement policies.
- 8.11 The US is signatory to the WTO Government Procurement Agreement (“GPA”) which contains obligations on its signatories to open their procurement markets to international competition. However, the US’s obligations under the GPA are limited. Only 37 states and the federal government are signatories to the GPA. This means that any municipal contracts are not subject to the GPA, even where such municipal projects are funded by the federal government. The relevant municipality will be considered the “owner” of the project for the purposes of the GPA and such federal funding will be considered “assistance” under the GPA and expressly carved out of its scope. Under the GPA, parties may agree thresholds for the provisions to apply on a reciprocal basis through free trade agreements.

Above: Tappan Zee Bridge under construction in Tarrytown, New York, Westchester County, USA. November, 2016,

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9. IMPROVING DEFENCE COOPERATION

- 9.1 The US and the UK already work closely together in the fields of defence and security, and have significant investment in defence industries in each other's territories. There are a number of measures that could be taken to improve trade in this sector, which would deliver both economic benefits and more competition and innovation. It has been suggested that the process under Section 811 of the Fiscal Year 2018 National Defense Authorization Act ("NDAA"), which mandates a Defense Department study of ways to improve the integration of the US defence industrial base, including Britain and Australia should be initiated, to find ways to collaborate with allies and build on trade in this area.⁵⁰
- 9.2 The Committee on Foreign Investment in the United States ("CFIUS") is an inter-agency committee authorised to review transactions that could result in control of a US business by a foreign person ("covered transactions"), in order to determine the effect of such transactions on the national security of the US. CFIUS has powers to investigate and approve any such covered transaction, including powers to impose conditions to mitigate a threat to US national security (addressed below), or it may refer the matter to the President for final action. The President holds ultimate authority to prohibit or unwind a transaction where there is credible evidence that the transaction threatens to impair US national security and the threat cannot be adequately mitigated.⁵¹
- 9.3 The CFIUS review process is regulated by a statutory-mandated timeline and ranges from 30 to 90 days, depend on whether CFIUS requires a full investigation period of up to 45 days and presidential review. The confidential review process includes consideration of certain statutorily enumerated factors that CFIUS considers when reviewing a covered transaction. These include, for example, ensuring the domestic capability and capacity necessary to fulfil national defence requirements, the impact of a transaction on US technological leadership in an area affecting national security, the potential effects on US critical infrastructure, effects on critical technologies, long-term US energy needs, whether the transaction involves an acquirer that is controlled by a foreign government, and whether the home country of the acquirer adheres to US policy on non-proliferation and export control requirements.⁵²
- 9.4 CFIUS assesses transactions by way of a three-part "national security analysis". First, CFIUS evaluates the foreign person to determine whether it has the ability or intent to exploit or cause harm. Second, it considers the US business being acquired, including any relationship to weakness or shortcoming in the US national defence or any susceptibility to impairment of US national security. Finally, it evaluates the risk of potential threat or vulnerability caused as to US national security as a result of the intended transaction. If CFIUS concludes there is a potential threat to national security, it may require the parties to the transaction to

50. Nile Gardiner and Ted Bromund *The Trump–May White House Meeting: Five Key Recommendations for Advancing the Special Relationship* (January 2017) <http://origin.heritage.org/research/reports/2017/01/the-trumpmay-white-house-meeting-five-key-recommendations-for-advancing-the-special-relationship>

51. http://www.ofii.org/sites/default/files/OFII_CFIUS_Primer.pdf

52. *Ibid.*



enter into a mitigation agreement which might include a governance measures, security requirements, and monitoring/verification mechanisms, among other conditions.⁵³ Not all transactions are subject to CFIUS review. The parties may choose to submit their transaction to CFIUS review, but there is considerable discretion in the process which makes outcomes unpredictable.

- 9.5 The US and UK might seek to agree a more streamlined review process for UK-based businesses. This could come in the form of a light-touch review process through mutual recognition of any transaction involving a business that can demonstrate it has been legally incorporated in the UK (e.g. a presumption that all UK businesses will not offer a threat to US national security), or through an expedited review process (e.g. where any review by CFIUS of a transaction involving a UK business is prioritised and processed faster than the current statutory timescales).⁵⁴

Above: US Air Force F-16 fighter jet at the International Aerospace Exhibition ILA, Berlin, 2014.

©VanderWolf Images / Shutterstock.com

53. *Ibid.*

54. The presence of Chinese products in the UK supply chains will complicate any attempt to agree CFIUS review.

10. IMPROVING PROPERTY RIGHTS PROTECTION— INTELLECTUAL PROPERTY

- 10.1 The UK and US share a commitment to protection of intellectual property protection (“IPR”). The EU has extended IPR into areas such as the EU’s broad interpretation of Geographical Indications (“GIs”) which have harmed UK and US interests alike (especially in areas like wine and champagne production).⁵⁵ Apart from Scotch Whiskey, the UK’s interests in GIs are limited and opportunistic. For example, simply because they are available, incumbent producers often take advantage of them.^{55a}
- 10.2 Other like-minded countries in the Prosperity Zone would welcome the elimination of GIs as they are all negatively impacted by them. As mentioned above, the World Wine Trade Group, consisting of Australia, Canada, Chile, Georgia, New Zealand, South Africa, and the US have campaigned on various aspects of wine designation and will be anxious to secure more openness from the UK than from the EU.
- 10.3 Apart from this area, UK and US IP law align well in terms of overall objectives. By contrast, some EU countries are still on the intellectual property watch-lists maintained by the US government such as Bulgaria, Greece and Romania.⁵⁶ The UK was not mentioned in the National Trade Estimate of 2017 indicating its approach to IPR and their protection is better than other EU member states.
- 10.4 Although the US and the UK both maintain a high level of IPR protection, it should be noted that the IPR chapter of the TTIP was one of the most contentious in negotiations between the US and the EU. Problematic discussions arose relating to internet service provider liability, finding commonalities between EU and US privacy, copyright policies and patent term extensions, protection of test data and patent linkage.⁵⁷

⁵⁵ <https://www.agra-net.com/agra/agra-europe/policy-and-legislation/trade-policy/us-report-identifies-eu-s-agricultural-barriers-to-trade-547308.htm>

^{55a} See for example the award of protected status to Welsh laver bread <http://www.bbc.co.uk/news/uk-wales-39949753>

⁵⁶ <https://ustr.gov/sites/default/files/USTR-2016-Special-301-Report.pdf>

⁵⁷ [http://www.europarl.europa.eu/RegData/bibliotheque/briefing/2014/140760/LDM_BRI\(2014\)140760_REV1_EN.pdf](http://www.europarl.europa.eu/RegData/bibliotheque/briefing/2014/140760/LDM_BRI(2014)140760_REV1_EN.pdf)

11. THE POSSIBILITIES FOR FINANCIAL SERVICES LIBERALISATION

- 11.1 There is an opportunity for the UK and US to cooperate on financial services with a view to establishing more pro-competitive regulation around the world. Indeed, some of the major financial centres around the world, such as Hong Kong, Tokyo, New York, London and Zurich might be interested in working together on such an endeavour. In this context the UK-US FTA is a vital part of the process.
- 11.2 The UK is relatively open in financial services. Greater co-ordination and recognition of home state regulation could deliver significant gains to the US and the UK, and to the global economy if it results in greater innovation and consumer welfare enhancing financial products. Our paper *A New UK/EU Relationship in Financial Services—a Bilateral Regulatory Partnership* sets out a model for how this could be achieved.⁵⁸
- 11.3 In mutual recognition for financial services, there is already precedent for the US adopting mutual recognition, such as the mutual recognition arrangement signed by the US Securities and Exchange Commission (“SEC”) and the Australian Securities and Investment Commission (“ASIC”) in 2008. This provided the framework for the authorities to consider regulatory exemptions that would permit US and eligible Australian stock exchanges and broker-dealers to operate in both jurisdictions, without requiring them to be separately regulated in each country. An Enhanced Enforcement MOU and a new Supervisory MOU allowed for greater regulatory cooperation and coordination between the SEC and ASIC. The intention was to provide US and Australian investors and businesses easier and more competitive access to each other’s markets. The US also has accords in place for mutual recognition and substituted compliance in some fields, such as central counterparties. The US and the UK should be able to build on this bilaterally and working in global fora.
- 11.4 In the US, the fragmentation of insurance regulation on a state basis is a significant barrier that could be addressed. The International Monetary Fund reported that the existing complexity and fragmentation bring risks of a lack of consistency and of failure to act on gaps or weaknesses in regulation with sector or system-wide implications.⁵⁹ The size of each insured population and how insurance risk is shared also has an impact on consumer pricing. Small employers, groups and individuals often find insurance coverage more expensive than larger groups such as government programmes and large employers, due to providers finding it more difficult to cross-subsidise with a smaller risk pool. There is also generally a lack of supervision of the insurance providers from a federal level, and rules vary from state to state. Ideally, the US should look to introduce a single insurance regulation, recognised on a state-wide basis, with a centralised supervisory body to enforce compliance by insurance providers. This might have the ancillary benefit of helping the US healthcare insurance market become more competitive.

58. <http://www.li.com/activities/publications>

59. IMF Country Report No. 15/90 *United States: Detailed Assessment of Observance of Insurance Core Principles* (April 2015)

12. TELECOMMUNICATIONS

- 12.1 The US has complained about a perceived two tier structure on costs of termination of international traffic in the EU. If the UK is outside the EU, it may be subject to this as well. In any event the parties should seek to include a reciprocal requirement to enforce cost-oriented interconnection in any FTA between them.

Below: AT&T (American Telecommunications Corporation) Retail Store. Indianapolis 2016.

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Shutterstock.com



13. DIGITAL SINGLE MARKET

- 13.1 The Audio Visual Media Services Directive (“AVMS”) requires minimum local content in television broadcasting in all member states, and will be updated as part of the EU’s Digital Single Market Programme to include ‘on-demand’ content through on-line channels. The UK will have to retain local content rules for broadcast media when it is outside the EU, as this is governed by a separate international convention (the Council of Europe Convention on Transfrontier Television) that the UK will still be a member of. This will be necessary for UK operators to benefit from continued access to the European television markets. The UK will in any event be carrying all EU laws and regulations into national law, so this will include the AVMS. The UK will in any event be carrying all EU laws and regulations into national law, so this will include the AVMS. However, there are provisions of this directive that the UK should review in due course, potentially as part of the trade agenda with the US. AVMS may therefore represent a soft base-line for the regulatory part of the negotiations.
- 13.2 TPP was the first agreement of its type to contain provisions relating to digital trade and the digital market and promotion of electronic commerce.⁶⁰ TPP sought to remove existing barriers to transfer of data by preventing the localisation of data and prohibiting digital customs duties. In addition, the TPP encourages governments to cooperate on matters of cyber security and banning parties from implementing certain arbitrary policies banning the use of technologies such as encryption or VPN on the basis that they threaten security. The agreement between the US and the UK will provide the opportunity to build on this shared ideal, to ensure that both parties benefit from a free and competitive flow of digital services.

⁶⁰ <https://ustr.gov/sites/default/files/TPP-Promoting-Digital-Trade-Fact-Sheet.pdf>

14. DATA PROTECTION—THE TENSION BETWEEN DATA FLOW AND DATA PRIVACY

- 14.1 There is a philosophical difference in the approach of the US and the EU to data. The US's businesses have loudly advocated for data flow. Many US firms are at the forefront of the "big data" and "Internet of Things" revolutions. In order for this "Fourth Industrial Revolution" to deliver its potential, data will have to easily flow across businesses and geographies. In Europe, by contrast citizens, concerned about the use of their private data appear to have won the battle with business and the EU is much more protective of privacy with the resulting restrictions on data flow. This is an area where there will either be a way that data can flow across the US-UK-EU supply chain, or it cannot. UK-US FTA negotiations must seek to find this path.
- 14.2 The EU General Data Protection Regulation ("GDPR") will be in place with effect from May 2018. The GDPR contains very stringent protections for data (how it is held, who holds it and what it can be used for), and purports to extra territorial reach wherever personal data of EU citizens is processed. It also includes specific controls on the transfer of personal data to non-EEA countries who are not officially recognised by the Commission as providing for an adequate level of protection of personal data (so-called 'white-listing'). This will make it difficult for data to flow to the US without satisfying a number of safeguards. This, in turn, will create significant issues with the US, for whom data flow is a very important deliverable in any trade agreement, but the UK will not be in a position to relax these requirements without losing its own white listing (which it will hope to have in place as at the date of Brexit).
- 14.3 The US is not whitelisted, due to a number of issues in its approach to data protection (or lack of it) that do not satisfy Commission requirements. The alternative solution in operation is the Privacy Shield (which replaces the Safe Harbor scheme), under which businesses can operate certain measures to protect personal data and can therefore receive personal data from the EEA without further safeguards. The Privacy Shield is designed to allow companies in the EEA and Switzerland to transfer data from their home jurisdictions to the US without putting further safeguards in place. As a minimum, it can be expected that the UK will replicate the Privacy Shield determination.

15. HEALTH SERVICES

15.1 The socialised healthcare system operated through the British National Health Service (“NHS”) means that there are substantial barriers to the healthcare market in the UK. Some services are provided by private contractors under contract to the NHS, and US providers have invested in such business, mainly through acquisition. For example, US-based Acadia owns the Priory Group, whilst the Hospital Corporation of America owns several private hospitals in Britain. However, it is unlikely that large or significant parts of the NHS would be opened up to provision by foreign companies, although government procurement rules could be opened up to allow US firms to bid for NHS contracts in the same way as European firms. In reality, the structure and financing of the NHS mean there is little appetite to invest in this market,⁶¹ and the political imperative to protect, and be seen to protect, the NHS mean that for a trade deal to progress expeditiously, it would be preferable not to include NHS services. As in all services areas, the UK could simply reserve the sector. Progress could be made in the private healthcare market, however, it should be noted that the private healthcare sector in the UK is less attractive because it has to compete with a state-supported entity.

⁶¹ <http://www.economist.com/news/britain/21716662-question-what-firm-would-invest-national-health-service-american-trade-deal>

16. CHEMICALS: AN EXAMPLE OF THE PRECAUTIONARY PRINCIPLE

- 16.1 Regulation of the chemicals sector in the EU is perhaps subject to more complaints by non-EU businesses than any other sector. EU chemicals regulation, which is led by Regulation (No 1907/2006) regarding the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH"), which applies the precautionary principle to this sector.
- 16.2 REACH is a framework for chemicals manufacture and use in Europe with its stated aim to ensure that chemicals produced, imported, sold and used in the EU are safe.⁶² There is a registration/data generation requirement within REACH which obliges manufacturers to gather information relating to new and existing chemicals used within their business and submit such information to the European Chemicals Agency (ECHA) for review and for inclusion within a 'central chemicals database' to be administered by the ECHA. Behind Germany, the UK has the second highest number of REACH registrations at 5,488.⁶³ REACH reduces third country exports to the EU by increasing cost and, in some cases, barring products from entering the single market, prompting concerns that such actions are not always necessary and/or proportionate to the potential risk posed.
- 16.3 For example, in 2013, Germany started campaigning for beryllium, a metal that is used in defence and commercial applications to be included on the REACH list of substances of very high concern for authorisation. Such inclusion would have placed onerous obligations on imports of products including use of such metal into the EU and effectively created a barrier to imports of the metal from the US which, according to the Office of the United States Trade Representative ("USTR"), accounted for 40% of the US's sale of the metal. Of particular issue for the USTR was that beryllium was difficult to replace with any other substitute (it has definitive properties such as strength, low weight, and resistance to chemical deterioration). It was submitted by the USTR that although it recognised the health risks from exposure to beryllium, it believed that the appropriate way to manage that risk was by controlling human exposure rather than effectively banning the substance from import into the EU.⁶⁴
- 16.4 In light of this, it is key for the UK to be able to sensibly assess the risks of imported products on a case-by-case basis and have the option to create practical solutions when dealing with such products, so as not to lose the benefit of products with no substitutional equivalent. The UK's position on REACH should align to its position on standards (as outlined in section 18 below).
- 16.5 The UK and US will have to agree some science-based approach to product risk that would enable product MRAs with the EU for both parties.

62. <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3A121282>

63. <https://echa.europa.eu/regulations/reach/registration/registration-statistics/overview-all-countries>

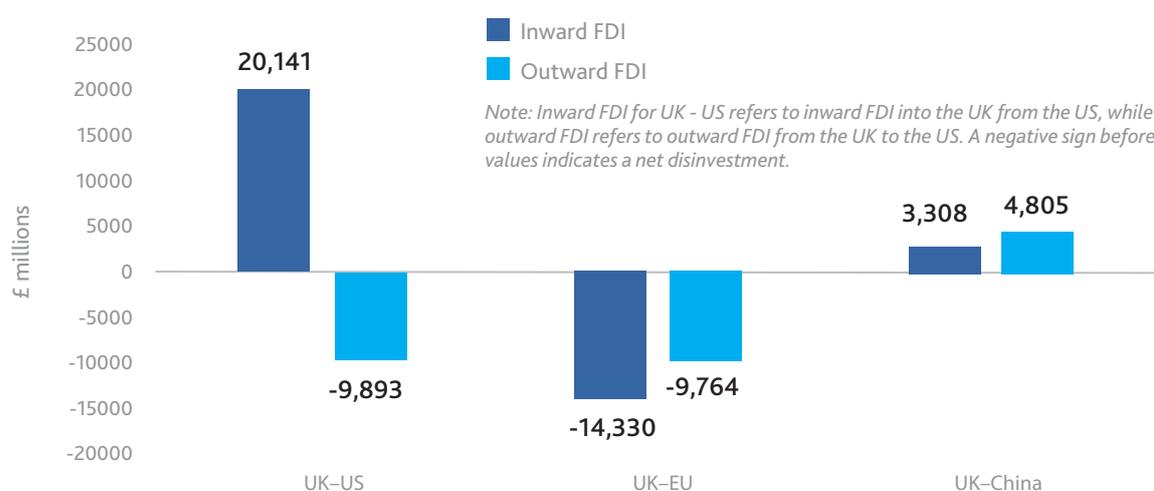
64. <https://ustr.gov/about-us/policy-offices/press-office/factsheets/2016/march/ustr-successes-reducing-technical>

17. MANAGING TALENT

Below: Figure 2: FDI flows, 2015

Source: UK data from ONS, Inward Foreign Direct Investment involving UK Companies, 2015, ONS, Outward Foreign Direct Investment involving UK companies, 2015, US data from OECD, FDI Financial Flows. US data converted from USD to GBP using the OECD exchange rate for 2015.⁶⁶

- 17.1 One of the major issues that the UK and US should agree is how to ensure the best talent is available to firms in both jurisdictions. There is such a shared set of values, language and laws between the UK and the US that it should be possible to ensure a situation where British and American people can live and work much more easily in each other's countries. In particular, given that the UK-US investment relationship is the strongest in the world (as shown in figure 2 below) it should be possible to agree "mode 4 services" arrangements between these two countries. Mode 4 services means the presence of persons of one WTO member in the territory of another for the purpose of providing a service.⁶⁵
- 17.2 The US and the UK should seek to agree reciprocal rights for movement of people between the two countries. Following its exit from the EU, the UK may seek to establish a needs-based immigration policy, which might seek in part to replicate a similar mechanism to the existing US H1-B visa. The H1-B visa permits US employers to recruit foreign workers in speciality occupations on a temporary basis. Workers under the H1-B visa programme are authorised to remain in the US for 3 years, extendable to 6 years. However, in the event that the relevant occupation ceases, holders are required to apply for an alternative status,



⁶⁵ https://www.wto.org/english/tratop_e/serv_e/mouvement_persons_e/mouvement_persons_e.htm

⁶⁶ Notes: Inward FDI for UK—US refers to inward FDI into the UK from the US, while outward FDI refers to outward FDI from the UK to the US. A negative sign before values indicates a net disinvestment.

find another employer or leave the US. Such speciality occupations particularly include skilled and professional work such as architecture, engineering, mathematics, law and accountancy. With the recent reforms instructed to the H1-B visa procedure by virtue of the "Buy American, Hire American" Executive Order, signed by the president on 18 April 2017, a discussion between the US and UK on this issue should be sought as soon as possible.

- 17.3 Special provisions for the H-1B program for the UK could be agreed, where there would be a mechanism for especially skilled and professional workers. We could also make it easier for our university students from the other country to stay on after their degrees to work in the host country. An automatic right to remain (or green card, in US parlance) should be in place for advanced degrees in certain courses (for example, science, technology, engineering and mathematics, or "STEM").

18. IMPROVING THE STANDARDS SETTING ENVIRONMENT BETWEEN BOTH COUNTRIES

- 18.1 This is a key area for the UK to get right in the context of its other agreements, and one where there is a very significant America interest. It would not be in either the UK or US's long term interests for the UK to simply agree to be locked in to the EU standards and product regulation. If this occurs, the UK will become a propagator of EU standards and product regulation all over the world. It will significantly imperil the ability of the UK to come to agreements with other countries and will threaten the UK's independent trade policy (as described in *A Blueprint for UK Trade Policy*.⁶⁷ Instead the best approach is to strengthen the networks of MRAs between the US and UK, and separately between the UK and EU. This also recognises the process which has already occurred (the six MRAs between the US and EU were first negotiated in 1997 (see section 17.46 below)).
- 18.2 Standard setting and the interaction between standards and mandatory legal product requirements are materially different between the UK (under harmonised EU regulations and processes) and the US, and was a major stumbling block in TTIP negotiations.
- 18.3 The overall approach to standard setting and regulation differs quite considerably between the US and a UK which has had its regulatory system decided in Brussels over forty years. The EU approach to standard setting is much more centralised. The US and EU already have a framework agreement in the areas of conformity assessment and mutual recognition in a number of sectors. Appendix 2 contains an analysis of Mutual Recognition Agreements ("MRAs") between the US and EU.

RATIONALE FOR MRAS AND THEIR RELATIONSHIP TO CONFORMITY ASSESSMENTS

- 18.4 MRAs refer to negotiations to achieve the mutual acceptance of conformity assessment procedures: or the testing, certification, accreditation, and quality system registration of products and processes, which are intended to reduce barriers to trade.⁶⁸ MRAs can prevent new barriers appearing as nations develop more complex infrastructure for testing and approving goods and services, including in emerging technological fields. Therefore, understanding and improving these processes is one of the most important areas in creating new trade deals, including for developed economies.
- 18.5 While tariffs have been cut globally, there has been an increase in other mechanisms to prevent access of goods to national markets. The costs of traditional types of protection are much discussed, but less attention has been paid to analysing such non-tariff barriers to trade ("NTBs"). With the decrease in transatlantic tariff barriers between the US and EU, firms became more concerned with what they termed duplicative regulatory compliance costs, pressing for their removal. As a result of the MRA between the two, private testing bodies often test products in the manufacturer's place of production on one side of the Atlantic in accordance with standards set

67. <https://lif.blob.core.windows.net/lif/docs/default-source/default-library/170427-final-trade-blueprintweb.pdf?sfvrsn=0>

68. Conformity assessment is defined by the International Organization for Standardization/International Electrotechnical Commission Guide 2: 1996 as: 'any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.' Typical examples of conformity assessment activities are sampling, testing and inspection, evaluation, verification and assurance of conformity (supplier's declaration), certification, registration, accreditation, and approval as well as their combinations. Conformity assessment may also be the process by which it is determined that a product's design meets a specification or standard (NIST, 2000).

on the other, under a sub-contracting arrangement with the responsible certification body in the importing jurisdiction.

- 18.6 MRAs and efficient international standards regimes accomplish several important goals, including facilitating the diffusion of innovative technologies and production techniques and helping create global economies of scale. Conformity to standards is understood to be where exporters' costs are likely to grow in the future, and this pressure can be expected to appear again in the context of a UK-US trade deal. However, such MRAs allowing the recognition of respective domestic conformity assessment procedures as valid for export can become both more comprehensive in terms of products—and more effective—with a new UK conformity assessment system presumably to be constructed following the UK departure from the European Union.
- 18.7 The following discussion will attempt to understand the US and EU conformity assessment structures, opportunities for MRAs, and their competition implications beyond a UK-US MRA itself.
- 18.8 Through establishing an MRA, each party has the ability to test, then certify, products against the regulatory requirements of the other party in the agreement, within its own territory and prior to export.⁶⁹ This occurs where countries need third-party certification for particular products, so is typically useful for products presenting possible risks to the public, or whose technical or chemical capacities and risks are unknown, and which must be submitted to stringent technical control.
- 18.9 A product being evaluated in its country of production is believed to improve efficiency and competition: it reduces time, expense, and/or the unpredictability involved in obtaining approval. These savings can be important, especially where a market is distant; where rejection of products by destination country agencies would mean delay or increased shipping costs; where a sector is highly regulated; where testing is done prior to and after export, or where early marketing may be vital for competitiveness.⁷⁰ These are understood to be especially useful for small and medium sized enterprises ("SMEs") lacking the resources to understand or access the regulatory system of a third country, as MRAs enable testing and certification to be done locally (the benefits to SMEs also imply helping create a more competitive business ecosystem). In addition, MRAs can create longer-term regulatory benefits, including reducing the risk of conformity assessment being used to protect domestic manufacturers (e.g. where testing and certification is carried out in conjunction with research for domestic industrial interests).⁷¹
- 18.10 MRAs do not themselves require harmonisation of regulatory procedures, or of technical standards, although they highlight the differences between regulatory systems of the parties involved, and therefore point to areas where their improvement or harmonisation could be beneficial. MRAs can thus be used as statements that lead to improved regulatory agreements for larger trade zones, and can be gradually revised in this manner. Thus in most instances, MRAs will operate where parties' underlying rules remain different, but can be used as an opportunity to improve conformity assessment. Thus in general, the greatest gains are to be made where mutual recognition is achieved against a background of harmonised or equivalent rules, deepening competition.
- 18.11 Meanwhile, in some sectors with shorter life cycles (such as ICT products), the benefits of gradual harmonisation of conformity assessment by removing the costs to industry of national differences in standards or technical regulation may be more important than MRAs themselves. Here mutual recognition may be seen as a useful step towards regulatory convergence.⁷²

69. Park, C.H. (2001). *Economic Analysis of Conformity Assessment*. Korea Information Society Development Institute, Report.

70. Schmidt, S.K. (2007). 'Mutual Recognition as a New Mode of Governance.' *Journal of European Public Policy*, 14: 5, pp.668-687.

71. Park, C.H. (2001). *Economic Analysis of Conformity Assessment*. Korea Information Society Development Institute, Report.

72. The welfare implications of MRAs are discussed in p.32-36 of Park, C.H. (2001). *Economic Analysis of Conformity Assessment*.

18.12 The following sections outline the US and EU standards and conformity assessment systems as they currently exist, the challenges in MRA negotiations between them, and begins to establish how the development of a new UK conformity assessment system for standards can ease the creation of MRAs in new trading arrangements with the US in particular, with a view to longer-term conformity assessment harmonisation.

THE US AND EU STANDARDS AND CONFORMITY ASSESSMENT SYSTEMS:

US system—Overview of the decentralised rationale of the system

- 18.13 In the US standards development system many US voluntary consensus standards organisations are coordinated by the private, nonprofit American National Standards Institute (“ANSI”). ANSI sets guidelines for groups to follow in managing the consensus-seeking process for establishing standards in a ‘fair and open manner’, accrediting many standards-setting organisations for compliance with these guidelines. It also approves many of the standards these organisations produce, designating them American National Standards.
- 18.14 ANSI has a decentralised organisational structure, its intent being for standards developers and users by industry to manage standards development themselves. ANSI members in the IT industry emphasise international standardisation, and are free to pursue its coordination, while consumer and workplace safety and health standards are developed by organisations with a focus on national standards.
- 18.15 ANSI is a nonprofit organisation, and membership includes approximately 1,300 firms, 35 government agencies, and over 260 technical, trade, labour and consumer groups. ANSI arose from the American Engineering Standards Committee, formed in 1918 as a federation of Standards Developing Organizations (“SDOs”), and was renamed the American National Standards Institute in the 1960s, its principal missions being to coordinate the voluntary consensus standards development system, promote awareness and use of voluntary standards, and represent US interests in international standardisation bodies. ANSI does not need to approve government-set standards.

Standards Developing Organisations (“SDOs”) under ANSI

- 18.16 SDOs can be divided into membership organisations; professional societies (including academic); and industry associations (by sector) (while ANSI itself can be called an SDO). For instance, the 20 leading nongovernment standards developers by number of standards produced cover a range of sectors: electronics; aerospace; automotive and mechanical engineering; chemicals; and cosmetics. Most formal standards used in the US private sector are developed by private SDOs.
- 18.17 Compared to most systems, the institutional structure of the US standards system is very decentralised, with over 400 private standards developers. Most SDOs are organised around a given industry, profession, or discipline, and around 275 engage in ‘ongoing’ standards-setting; the others have developed standards before, sometimes updating these.

Table 1: Examples of SDOs

FEDERAL GOVERNMENT
Department of Defense
General Services Administration (nondefense procurement)
Other federal (primarily regulatory)
Examples: Environmental Protection Agency, Occupational Safety and Health Administration, Federal Communications Commission
PRIVATE SECTOR*
Scientific and Professional Societies
Examples: American Society of Mechanical Engineers (ASME), Institute of Electrical and Electronics Engineers (IEEE)
Trade Associations
Examples: National Electrical Manufacturers Association (NEMA) Computer and Business Equipment Manufacturers Association (CBEMA)
Standard-Developing Membership Organisations
Examples: American Society for Testing and Materials (ASTM), National Fire Protection Association (NFPA)

*not including de facto industry standards

(Source: National Research Council, 1995)

18.18 After review, comment, and approval by an SDO's oversight board and membership at large, the organisation may publish a standard. If the SDO uses ANSI-accredited procedures, it may choose to have the standard approved and distributed by ANSI as an American National Standard. ANSI does not review the standard for technical merit but, rather, certifies it was developed in an open, consensus-oriented manner and does not seriously conflict with or duplicate current standards. The standard's usefulness to interested parties in the relevant market sector—manufacturers, purchasers, regulators, testing laboratories, certifiers, and others—largely determines whether it gains widespread acceptance. A technologically obsolete, commercially unviable standard will be neglected and will be discontinued by the SDO.⁷³

18.19 The following table defines the three principal types of standards by development process.

73. National Research Council. (1995). *Standards, Conformity Assessment and Trade into the 21st Century*. Washington, DC.

Table 2: Types of US standard

DE FACTO STANDARD	A standard arising from uncoordinated processes in the competitive marketplace. When a particular set of product or process specifications gains market share such that it acquires authority or influence, the set of specifications is then considered a de facto standard. Example: IBM-compatible personal computer architecture
VOLUNTARY CONSENSUS STANDARD	A standard arising from a formal, coordinated process in which key participants in a market seek consensus. Use of the resulting standard is voluntary. Key participants may include not only designers and producers, but also consumers, corporate and government purchasing officials, and regulatory authorities. Example: photographic film speed--ISO 100, 200, 400, etc., set by International Organization for Standardization (ISO)
MANDATORY STANDARD	A standard set by government. A procurement standard specifies requirements that must be met by suppliers to government. A regulatory standard may set safety, health, environmental, or related criteria. Voluntary standards developed for private use often become mandatory when referenced within government regulation or procurement. Example: automobile crash protection—air bag and/or passive seat restraint mandated by National Highway and Traffic Safety Administration

(Source: National Research Council, 1995)

18.20 The largest proportion are developed within the second type, comprising consensus-building activities among private firms, technical experts, customers, and other interested parties (these groups write standards through formal discussion, drafting and review process, members forming consensus on the best specifications for industry and public need, with standards published for voluntary use throughout industry). Standards arising from these processes are termed 'voluntary consensus' standards. Examples range from dimensions of valve fittings in household plumbing to performance characteristics of automotive structural materials. Various private organisations produce voluntary consensus standards, including nonprofit, standards-setting membership organisations and industry and trade associations.

18.21 The public sector also plays a major role in the US standards system. Federal, state, and local government agencies are active in developing standards. Those written by federal agencies for regulatory and procurement purposes comprise more than half the total national standards. These are 'mandatory standards', reflecting imposition through legislation/regulation or via contractual arrangements for government procurement⁷⁴ (although these are developed outside the ANSI-coordinated voluntary consensus system, the mandatory and voluntary standards overlap. Many government standards refer to voluntary standards, which then become mandatory).

18.22 The Department of Defense and the General Services Administration, respectively constitute the bulk of federal standards, the remaining standards—mainly technical regulations—being produced by a range of departments and agencies (see Table 3, below). Regulatory standards centre on protecting public health and safety, and examples include the Food and Drug Administration ("FDA"), Occupational Safety and Health Administration ("OSHA"), and the Environmental Protection Agency. Increasingly however, government agencies meet their obligations not by participating in (and adopting) the results of voluntary consensus standards development.

74. National Bureau of Standards (NBS) Special Publication 681. (1984). *Standards Activities of Organizations in the United States* (R.B Toth, Ed.)

Table 3: US government standards developers

<p>Agriculture, Department of</p> <ul style="list-style-type: none"> Agricultural Marketing Service Federal Grain Inspection Service Field Management Division Standards and Procedures Branch Food Safety and Inspection Service Foreign Agricultural Service Forest Service Engineering Staff Information Resources Management Planning, Review, and Standards Division Packers and Stockyards Administration Livestock Marketing Division Rural Electrification Administration <p>Commerce, Department of</p> <ul style="list-style-type: none"> Bureau of the Census Federal Coordinator for Meteorology National Institute of Standards and Technology National Computer Systems Laboratory National Engineering Laboratory and Law Enforcement Standards Laboratory Technology Services—Voluntary Product Standards National Oceanic and Atmospheric Administration National Marine Fisheries Service National Environmental Satellite, Data, and Information Service National Weather Service National Telecommunications and Information Administration Institute for Telecommunications Sciences U.S. Patent and Trademark Office Assistant Commissioner for Information Systems Assistant Commissioner for Patents International Patent Documentation Trademark Examining Operation 	<p>Consumer Product Safety Commission</p> <ul style="list-style-type: none"> Directorate for Engineering Sciences Directorate for Health Sciences <p>Defense, Department of</p> <ul style="list-style-type: none"> Office of the Assistant Secretary of Defense, Acquisition Defense Industrial Supply Center <p>Energy, Department of</p> <ul style="list-style-type: none"> Assistant Secretary for Defense Programs Building Technologies Building Systems and Materials Division Building Equipment Division Energy Information Administration Statistical Standards Environment, Safety, and Health Safety and Quality Assurance <p>Environmental Protection Agency</p> <p>Federal Communications Commission</p> <ul style="list-style-type: none"> Office of Engineering and Technology <p>General Services Administration</p> <ul style="list-style-type: none"> Information Resources Management Federal Supply Service Commodity Management Public Building Service <p>Health and Human Services, Department of</p> <ul style="list-style-type: none"> Centers for Disease Control National Institute for Occupational Safety and Health Food and Drug Administration Regulatory Affairs Health Care Financing Administration <p>Housing and Urban Development, Department of</p> <ul style="list-style-type: none"> Assistant Secretary for Housing—Federal Housing Commissioner Manufactured Housing and Construction Standards Division
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<p>Interior, Department of the</p> <ul style="list-style-type: none"> Minerals Management Service Rules, Orders, and Standards U.S. Geological Survey Information Systems Division National Mapping Division Water Resources Division <p>Labor, Department of</p> <ul style="list-style-type: none"> Mine Safety and Health Administration Standards, Regulations and Variances Occupational Safety and Health Administration Directorate of Safety Standards Programs <p>National Aeronautics and Space Administration</p> <ul style="list-style-type: none"> Occupational Health Safety, Reliability, Maintainability, and Quality Assurance Division <p>National Archives and Records Administration</p> <ul style="list-style-type: none"> Archival Research and Evaluation Staff <p>Nuclear Regulatory Commission</p> <ul style="list-style-type: none"> Nuclear Regulatory Research <p>State, Department of</p> <ul style="list-style-type: none"> U.S. National Committee for the International Telecommunications Union-Telecommunication Standardization Sector 	<p>Transportation, Department of</p> <ul style="list-style-type: none"> Federal Aviation Administration Federal Highway Administration Maritime Administration National Highway and Traffic Safety Administration Research and Special Programs Administration Standards Division United States Coast Guard Marine Safety, Security, and Environmental Protection Auxiliary, Boating, and Consumer Affairs Division <p>Treasury, Department of</p> <ul style="list-style-type: none"> Bureau of Alcohol, Tobacco, and Firearms National Laboratory Center Internal Revenue Service Standards and Data Administration U.S. Customs Service Commercial Operations Research Division—Laboratories and Scientific Services <p>Veterans Affairs, Department of</p> <ul style="list-style-type: none"> Acquisition and Material Management
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(Source: National Research Council, 1995)

18.23 This is also the field of the National Institute of Standards and Technology ("NIST") at the Department of Commerce ("DoC"). NIST (established in 1901 as the National Bureau of Standards, with responsibility for developing standards of weights and measures) is not a regulatory agency, but is active in aspects of public and private standard setting. In 1988 the bureau was given the mission of helping industry advance its performance in developing and applying technology. Scientists in its laboratories conduct research in a wide range of physical sciences, one goal being to advance the science of testing and apply the advances to standardisation.

Connection to International Standards Development

18.24 The two predominant international standards-setting bodies are the International Organization for Standardization (“ISO”) and the International Electro-technical Commission (“IEC”). ISO and IEC are private organisations developing standards in nearly all sectors of industry and technology. (The largest exception to their coverage is telecommunications, the area of the International Telecommunications Union (“ITU”).) ANSI is the US member of ISO and IEC, the latter through the ANSI-coordinated US National Committee. (In addition, the US has had success obtaining secretariats of ISO and IEC technical committees and subcommittees in industry sectors with high volumes of exports. For example, the US holds the secretariats of ISO/IEC JTC1 for IT; the ISO Technical Committee (TC)20, covering aircraft and space vehicles; ISOTC 61 for plastics; and ISO TC 67 for petroleum industry materials and equipment. All these committees set international standards in industry sectors that are among the top 10 US export industry sectors.)

Conformity assessment areas

- 18.25 Conformity assessment is the comprehensive term for measures taken by manufacturers, their customers, regulatory authorities, and independent, third parties to assess conformity to standards: a standard does not have the intended effect if products designed to conform to it do not actually do so. US conformity assessment is also relatively decentralised, consisting of four areas (the terms used being for manufactured products in particular, although the same concepts apply to processes and services).
- 18.26 The first area in US understanding is ‘manufacturer’s declaration of conformity’, an assessment by the manufacturer based on internal testing and quality assurance mechanisms; the second is ‘testing of products, parts, and materials’, done by independent, typically private laboratories for manufacturers; the third is ‘certification’, meaning formal verification by an unbiased third party through testing and other means, that a product conforms to specific standards (examples of certification include the Underwriters Laboratories product safety certificate). The final area is ‘quality system registration’, the result of independent audit and approval of the manufacturer’s quality system (a quality system being a management system, including procedures, training, and documentation, for ensuring consistency in product quality).⁷⁵

THE EUROPEAN UNION SYSTEM

Overview of standards and conformity assessment

18.27 Before the creation of the EU, each country imposed its own technical requirements, with varying standards and conformity assessment procedures forcing exporters to target smaller numbers of countries. The new laws which were created by Brussels at the end of the 1990s were called the New Approach Directives,⁷⁶ with regulation of relevant products fairly generic and broadly limited to ‘Essential Health and Safety Requirements’. The table 4 outlines the range of these:

⁷⁵ National Research Council. (1995). *Standards, Conformity Assessment and Trade into the 21st Century*. Washington, DC.

⁷⁶ National Institute of Standards and Technology (2000). NIST Special Publication 951: *A Guide to EU Standards and Conformity Assessment*. (Delaney and van der Zende, Eds.)

Table 4: The New Approach Directives

DIRECTIVE REF.	DIRECTIVE SUBJECT
90/396/EEC	Appliances Burning Gaseous Fuels
93/68/EEC	CE Marking Directive (Council Directive Amending Other Directives)
89/106/EEC	Construction Products
89/336/EEC	Electromagnetic Compatibility
96/57/EC	Energy Efficiency Requirements for Household Electric Refrigerators, Freezers, and Combinations Thereof
94/9/EEC	Equipment and Protective Systems in Potentially Explosive Atmospheres
93/15/EEC	Explosives for Civil Uses
96/48/EC	Interoperability of Trans-European High-Speed Rail System
95/116/EC	Lifts (Elevators)
73/23/EEC	Low Voltage Equipment
98/37/EC	Machinery, Safety of
96/98/EC	Marine Equipment
90/385/EEC	Medical Devices: Active Implantable
93/42/EEC	Medical Devices: General
98/79/EC	Medical Devices: In Vitro Diagnostic
90/384/EEC	Non-Automatic Weighing Instruments
94/62/EC	Packaging and Packaging Waste
89/686/EEC	Personal Protective Equipment
COM(93)322	Precious Metals (Not Formally Proposed)
97/23/EC	Pressure Equipment
87/404/EEC	Pressure Vessels, Simple
1999/5/EC	Radio Equipment and Telecommunications Terminal Equipment and The Mutual Recognition of Their Conformity
94/25/EC	Recreational Craft
88/378/EEC	Toys, Safety of

- 18.28 The point of the New Approach Directives was to eliminate differences between national laws, thus eliminating barriers to trade between member states. Differences in national standards, and testing and certification procedures however were also central trade barriers, and a new scheme for technical harmonisation was deemed necessary. This was implemented in two major Decisions: a) the Module Decision, and b) the regulation on CE Marking (detailed below). This policy was called the Global Approach, incorporating conformity assessment procedure into New Approach Directives.⁷⁷
- 18.29 First, the Module system varies in complexity. For instance, Module A permits manufacturers to take responsibility for conformity assessment, and if a product is manufactured to Harmonised Standards and the risk not unusually high (e.g. in most machinery), manufacturers can rely on internal manufacturing checks, compiling a Technical File, issuing a Declaration of Conformity to appropriate directives and standards, applies the CE mark and may place a product on the market. Some Modules (e.g. for active implantable medical devices) however could call for type examination, and a production quality assurance system. In Europe, these are designated by the Commission authorities, and are named Notified Bodies.⁷⁸

The EU standards institutions

- 18.30 The overall direction of standards is now set by the European Commission, issuing directives listing the relatively little-detailed 'essential requirements' for safety that regulated products must meet. The Commission has officially delegated to the private sector the writing of new technical standards linked to EU-wide essential requirements, but these directives set a required level of safety without dictating the means by which it should be achieved.
- 18.31 Pan-European technical standards are being developed, under contract with and funded by the Commission, by three private standards-developing organisations (in a much more *dirigiste* structure than in the US). These are the European Commission for Standardization ("CEN"), the European Commission for Electrotechnical Standardization ("CENELEC"), and the European Telecommunications Standards Institute ("ETSI"). The members of CEN and CENELEC are national standards bodies from across Europe; ETSI membership is more *ad hoc*, including national telecommunication agencies, manufacturers and industry associations. Standards developed by these organisations play a central role in determining the products that may be marketed in Europe.
- 18.32 CEN, CENELEC, and ETSI standards are not the only standards the EU will accept as meeting essential product directives—products complying with other standards are acceptable, as long as the alternative standards also meet essential EU requirements. The burden of proof in such cases however is on manufacturers. This means product approval is easier to obtain through compliance with the CEN/ CENELEC/ETSI standards, and direct participation in their standards-writing work is thus of clear benefit to firms marketing regulated products in Europe.
- 18.33 Unlike most US standards-developing organisations, CEN, CENELEC, and ETSI are not usually open to foreign participants, and US firms (for example) without major European subsidiaries

^{77.} *Ibid.*

^{78.} *Ibid.*

must use other avenues to influence their standard-setting work. An outline of the three main European standards-developing organisations is as follows:⁷⁹

CEN: *Comite Europeen de Normalisation* (European Committee for Standardization). Based in Brussels, CEN has a membership consisting of the national standards-writing organisations of 18 European countries (the EU and EFTA members). CEN develops voluntary European Standards in all product sectors excluding the electrical standards covered by CENELEC. With funding from the European Commission, CEN also writes standards to meet the 'essential requirements' for product safety mandated in EU product directives. The standards work programme is directed by seven sector boards, in building and civil engineering; mechanical engineering; IT; workplace safety; healthcare; heating and cooling; and transport and packaging.

CENELEC: *Comite Europeen de Normalisation Electrotechnique* (European Committee for Electrotechnical Standardisation), also based in Brussels and with 18 European standards bodies ('national electrotechnical committees') as members. CENELEC develops European Standards for electrotechnology, including electricity generation, consumer electronics, electromagnetic compatibility, and IT (however international standards developed by the International Electrotechnical Commission ("IEC") are the basis for 89 percent of CENELEC standards). Around 35,000 technical experts participate in the standards-writing committees of CENELEC.

ETSI: the European Telecommunications Standards Institute, based in Sophia Antipolis, France, but has a cooperation agreement with the CEN/CENELEC structure. Membership is composed of the public telecommunications administrations of EU and EFTA nations, as well as manufacturers and trade associations. ETSI develops European Telecommunications Standards in particular, which may be adopted as mandatory by European national telecommunications systems. To hasten the standards development process, ETSI has due process procedures that require less consensus than CEN and CENELEC.⁸⁰

18.34 It is also useful to note the role of the European Organization for Testing and Certification ("EOTC"):

EOTC: European Organization for Testing and Certification. In 1991, CENELEC and CEN (reluctantly) agreed with the EC for the founding of the EOTC, formed to coordinate national bodies engaged in the certification process. As the EOTC is to some extent a competitor to ETSI, this has caused confusion for business, and the replication of activity. The EOTC Council is composed of fifteen members from various industrial and national interests and is a coordinating body with the various other standards organisations above, while gathering ad hoc committees on various industrial sectoral questions. EOTC is intended as a monitoring forum to monitor industry concerns and opinion on standards and conformity.

79. Egan, M. (2001). *Constructing a European Market: Standards, Regulation and Governance*. Oxford University Press

80. National Institute of Standards and Technology (2000) states: 'There is a relationship between US standards activities and those in the EU. Two organisations, the American National Standards Institute (ANSI) in the United States, and the International Organization for Standardization (ISO) in Geneva, Switzerland, act as bridges to CEN, and ANSI, via the United States National Committee (USNC), and the International Electrotechnical Commission (IEC) in Geneva, Switzerland, act as bridges to CENELEC' (National Institute of Standards and Technology (2000). NIST Special Publication 951: *A Guide to EU Standards and Conformity Assessment*. (Delaney and van der Zende, Eds.)).

- 18.35 Each member state is responsible for overseeing the certification bodies within its own jurisdiction, and must notify the European Commission's Enterprise Directorate-General ("DG") of its approvals. These testing and certification laboratories thus called 'notified bodies'. However national organisations replace national standards with EU standards whenever they are decreed.
- 18.36 To the extent that European standards vary (without apparent justification) from international standards in equivalent sectors, they also represent barriers to imports from outside Europe (although this danger is somewhat reduced by the CEN and CENELEC pledges to defer writing standards when ISO and IEC standards exist or are under development in the same product sectors: this underscores the importance of US industry participation in ISO/IEC committee work). Direct participation in CEN, CENELEC and ETSI standards development is prohibited, however, for US firms without a very substantial European presence, but foreign firms have access to participate in the US voluntary consensus standards system.
- 18.37 Harmonised Standards are therefore standards that support European legislation, and have been a) mandated by the EC, b) developed by the European Standards Bodies above, c) address essential requirements of the New Approach Directives, and d) notification of their development has been published in the *Official Journal of the European Communities*.
- 18.38 As mentioned above, technically speaking the use of a Harmonised Standard is voluntary, in that manufacturers can choose to use a Harmonised or non-Harmonised Standard (e.g. a US standard). However using anything other than a Harmonised Standard will put the burden of proof that the product meets essential requirements on the manufacturer, and will sometimes not be recognised by insurers, lenders, retailers, conformity assessment bodies, and may limit acceptance of a product by the market, especially when a European Standard already exists.⁸¹ Meanwhile, as we have seen, in product sectors where third-party product testing, certification, or quality system registration is required by law, approval may be granted only by organisations designated, or 'notified', to the Commission by the member states as technically competent. Only 'notified bodies' give final product approval for the European market.
- 18.39 Certified products are identified with the European 'CE Mark', and those without the CE Mark cannot be marketed in Europe. The requirement that final assessments be performed by European notified bodies raises the costs of testing and certification to US manufacturers in many sectors (and the contrast with the US system presents an opportunity for a new voluntary/private-led system in the UK).
- 18.40 The CE Mark is 'not a quality mark, nor is it a mark for consumers. Intended for Member State authorities, it is the visible sign to those authorities that your product is in compliance with the New Approach Directives'⁸² (compliance also requires determining which directives apply to the product, as a product may be regulated by more than one directive). Most products covered by New Approach Directives can be self-certified by a manufacturer and do not require intervention of a Notified Body. To self-certify, manufacturers must assess product conformity to applicable directives, and standards if applied. Manufacturers may affix the CE mark to products, and prepare and sign the Declaration of Conformity, providing the manufacturer

81. National Institute of Standards and Technology (2000). NIST Special Publication 951: *A Guide to EU Standards and Conformity Assessment*. (Delaney and van der Zende, Eds.)

82. *Ibid.*

can prove conformity to applicable requirements (manufacturers must provide proof in the Technical File). Some (higher risk) products may not be self-certified, but must be subject to EU type examination through inspection by a Notified Body⁸³ (i.e. in Europe, or by a subsidiary or subcontractor, excluding MRA products).

- 18.41 Even with mutual recognition in place, a 142-page Commission report on the 'Evaluation of the Application of the mutual recognition principle in the field of goods' for the Commission suggests that the principle (*between* EU member states) 'is still not achieving its objectives', particularly as knowledge of the principle is generally at a rather low level among companies and member state authorities. Implementation is so problematic that *Business Europe* (a trade body) has complained that national standards are interfering with the goods' circulation. In the round, MRAs and harmonisation are more realistic in a condition of 'mutual trust between states'.⁸⁴

THE DIFFICULTIES THE US HAS FACED IN ITS MRAS WITH THE EU

- 18.42 The EU expectation of the negotiations was that an MRA with the US would create formal US government assurance that US entities within an MRA are competent to perform 'essential' services in inspection and certification. For US producers, before this, US firms had three ways to obtain required third-party certifications for the EU market: they could ship samples to Europe to be tested and certified through a European 'notified body', pay expenses for European inspectors to inspect their plants in the United States, or could have testing and certification performed by one of a number of US subsidiaries of European laboratories (in some product sectors they could also have testing performed by a US laboratory subcontracting to a European certifier. In this case, the US laboratory performs the tests, forwarding test data to a European laboratory for evaluation and final approval to obtain a CE Mark). However, without MRAs in a given sector, all three of those avenues exclude US testing laboratories from the final stage of certification, constituting a barrier to US exports. Under MRA, US organisations are also performing testing and certification of exports to the EU, as mutual recognition involves US government involvement in guaranteeing the competence of private US conformity assessment organisations before they are accepted by EU regulatory authorities.

- 18.43 The Office of the US Trade Representative and the Commission's Trade Directorate-General ("DG") led the negotiations of the MRA framework agreement. Each annex was negotiated by the regulatory agency or agencies responsible for the sector. On the European side, the process was simpler because of the centralisation of the relevant agency officials within DG Enterprise, and their experience of coordinating the goals of regulation and trade within a single market. In the US however, separate (and independent) federal agencies negotiated annexes.⁸⁵ Negotiations were slowed by European negotiators' concern about the complexity of the US conformity assessment system, with its variety of private certification systems. (They noted, for instance, the lack of a US national or North American mark for entry into the United States, Canada, and Mexico analogous to the European 'CE Mark', which may still allow in the UK-US context, the ultimate aim of more regional multi-country marks in the longer-term.) Brussels officials were also concerned about the ability of US regulators to guarantee competence and

83. *Ibid.*

84. Schmidt, S.K. (2007). 'Mutual Recognition as a New Mode of Governance.' *Journal of European Public Policy*, 14: 5, pp.668-687.

85. Nicolaidis, K. and Shaffer, G. (2005). 'Transnational Mutual Recognition Regimes: Governance Without Global Government.' *Law and Contemporary Problems*. 68, pp.263-317

quality of US conformity assessment bodies, and as a result in the US, NIST created the National Voluntary Conformity Assessment Program.

- 18.44 On each side of the Atlantic, businesses have worked through the Transatlantic Business Dialogue (“TABD”) to promote MRAs in policy.⁸⁶ TABD has since highlighted areas of concern and put pressure on officials to timetable MRAs (Paula Stern, former chair of the US International Trade Commission and advisor to TABD, stated, ‘TABD quickly established the Trans-Atlantic Advisory Committee on Standards, Certification and Regulatory Policy (“TACS”) to formulate recommendations, organised on a sectoral basis, for the elimination of regulatory barriers between the two economies’).⁸⁷
- 18.45 A number of studies of the MRAs assess what spurred these agreements, the actors participating in negotiation, the constraints on their implementation (both political and market forces), and ultimately the prospects and limits for their adoption in other areas (these papers may help inform future US-UK MRAs and how they can improve upon the US-EU agreement that has been signed).
- 18.46 One assessment of the 1997 US-EC MRA (and its six sectoral annexes, which are sometimes informally referred to as separate MRAs) suggests first that the US appears to have implemented most of the changes involved in the MRAs.⁸⁸ The US and EU entered into discussion on MRAs in eleven sectors: information technology, telecommunications products attached to public networks, medical devices, electrical safety, electromagnetic interference, pharmaceuticals, pressure equipment, road safety equipment, lawn mowers, recreational boats, and personal protective equipment such as helmets. Negotiators ultimately reduced this to six: telecommunications equipment, electromagnetic compatibility, electrical safety, recreational craft, medical devices, and pharmaceutical good manufacturing practices (a UK-US MRA(s) may as an early priority add the other five areas). Nicolaidis and Shaffer state: ‘It has proven impossible, however, to expand this approach to services in which individual US states wield most regulatory power’.⁸⁹
- 18.47 The MRA that was settled upon also established a new transatlantic structure for overseeing implementation. First, the MRA created a Joint Committee of US and EC trade officials meeting twice annually. Second, the annexes created Joint Sectoral Committees, overseeing the separate annexes’ implementation. These Committees are important in implementing the MRA, consisting of the actual regulatory authorities who must oversee the protection of health and safety on each side of the Atlantic. In some cases, however, collaboration between these regulatory authorities has reportedly been ineffective—see below).
- 18.48 Businesses and some government representatives hoped US-EU arrangements would be a stepping-stone for reaching MRAs with third countries, leading to increased access to East Asian markets for example. The WTO Agreement on Technical Barriers to Trade (“TBT”), discussed below, and the General Agreement on Trade in Services encourage and give legal support to the expansion of transatlantic MRAs, and can be used to expand future UK/US MRA(s) to broader areas. Under WTO rules, countries that do not ‘give mutual satisfaction’ to third countries offering ‘equivalent’ procedures or standards may be subject to WTO anti-discrimination claims under WTO most-favoured nations (“MFN”) clauses.

86. *Ibid.*

87. *Ibid.*

88. Shaffer, G. (2002). ‘Reconciling Trade and Regulatory Goals: The Prospects and Limits of New Approaches to Transatlantic Governance through Mutual Recognition and Safe Harbour Agreements’. *Columbia Journal of European Law*, 9: pp. 29-77.

89. Nicolaidis, K. and Shaffer, G. (2005). ‘Transnational Mutual Recognition Regimes: Governance Without Global Government.’ *Law and Contemporary Problems*. 68, pp.263-317

- 18.49 While the prospect of these claims remains relatively remote at this stage, business organisations like TABD are already using WTO agreements for additional leverage.⁹⁰ More importantly than potential legal claims, each new MRA puts pressure on third countries to enter into negotiations so that their firms are not disadvantaged—a likely ‘contagion effect’.⁹¹ Each MRA thus provides leverage to domestic firms to demand new MRAs (e.g. with third country counterparts) to equalise market access. The transatlantic MRA can thus be seen as a step towards the extension of MRAs globally.
- 18.50 With respect to MRAs and conformity assessments, research recommends developing a private-led ecosystem with lighter state oversight. By permitting ‘over-extended and under-resourced’ state agencies to outsource testing and evaluation to private bodies, state resource can be allocated to areas of higher concern, retaining ‘high product and process standards and post-market surveillance controls’. Research suggests that there is no necessary link between private certification and increased risk to public health and safety,⁹² provided certification processes are based on high health and safety standards and complemented by regulatory oversight. This means constructing systems whereby government agencies keep oversight of critical regulatory and procurement standards in public health, safety, environment, and national security, with assessment of conformity to those standards performed most efficiently by the private sector. Government should act in an oversight capacity, evaluating private sector organisations as competent to accredit testing laboratories, product certifiers, and quality system registrars.⁹³
- 18.51 As the US has given the NIST a mandate to phase out federally-operated conformity assessment activities, with government relying on private activities in all but the most vital cases for public health, safety, environment, and national security, the UK may also receive a similar private sector-led system, with the British Standards Institute (“BSI”) given an ANSI-type role in coordinating a private ecosystem of testing relationships, which can also be formally encouraged to develop transatlantic relationships to harmonise UK and US standards. In the US, standards-related trade issues are focussed to some extent on the duties of the Office of the USTR, while the NIST is also involved in helping the USTR in areas related to international standards (the UK may choose to adopt a similar structure in rejuvenating the BSI).
- 18.52 Under a policy of harmonisation of conformity assessment procedures—i.e. a more developed approach than less ambitious MRAs—regulators in separate jurisdictions agree to adopt the same substantive standards and procedures. This harmonisation facilitates trade as well as cross-border regulatory cooperation because of regulators’ comfort with similar standards. However, MRAs mean greater challenges for regulatory cooperation because of regulators’ unfamiliarity with foreign standards (under a policy of mutual recognition, regulators retain separate standards for internally-produced products, but agree to recognise the other jurisdiction’s standards for products imported from it).
- 18.53 The UK/US FTA and its MRAs allow the mutual development of the kind of private-led system as laid out in 17.50 above. This should be the focus of efforts to develop the UK-US relationship, starting with the expansion of MRAs into the 11 sectors original laid out in the 1997 US-EU MRA (see section 17.45).

90. Trachtman, J.P. (2006) *Embedding Mutual Recognition at the WTO*. Tufts University.

91. Nicolaidis, K. and Shaffer, G. (2005). ‘Transnational Mutual Recognition Regimes: Governance Without Global Government.’ *Law and Contemporary Problems*. 68, pp.263-317

92. Egan, M. (2001). *Constructing a European Market: Standards, Regulation and Governance*. Oxford University Press

93. *Ibid.*

WTO TBT CONTEXT

- 18.54 The UK-US agreement is an opportunity for the UK and US to mutually re-commit to the WTO Agreement on TBT agreement. The TBT review process has revealed a number of trade barriers in global trade in this area.
- 18.55 The TBT agreement, or Standards Code, was first incorporated into the Tokyo Round of GATT. TBT, which is binding on all members and aims to help support progress toward market liberalisation worldwide, has important implications for standards set by national, sub-national and regional governments (such as the EU), and private-sector bodies. Here we outline the central elements of the agreement, as well as areas of uncertainty in its implementation and its impact on trade. TBT was clarified in the Uruguay Round (completed 1994), as follows:
- 18.56 'The requirement of transparency and non-discriminatory procedures for issuing product approval was expanded to cover the range of conformity assessment procedures, including testing, certification, accreditation, and quality system registration; encourages mutual recognition of conformity assessment procedures between countries; expands coverage to nongovernmental and regional standards development.'⁹⁴
- 18.57 The TBT states explicitly: 'Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations.'
- 18.58 The TBT also states that technical regulations should not be maintained if the circumstances or objectives giving rise to their adoption no longer exist, or if the objectives could be approached in a less trade-restrictive way. Having been expanded to include standards for processes as well as products, the requirement of transparent and non-discriminatory procedures for issuing product approval was also expanded beyond testing and certification to cover the range of conformity assessment procedures. The TBT also applies the principles of national treatment and non-discrimination to product testing and certification programmes, and extends the obligation of national treatment and nondiscrimination to laboratory accreditation, recognition, and quality system registration programmes. As we discuss below, the TBT constitutes progress in extending rules to private standards organisations, such as the ANSI. The Code of Good Practice for the Preparation, Adoption and Application of Standards contained in Annex 3 of the TBT agreement also creates a foundation for extending rules to private standards bodies.
- 18.59 The TBT basis to encourage acceptance of the results of tests or laboratory accreditation across national borders is limited however, though Article 6 of the TBT Code exhorts signatories to move toward harmonisation of conformity assessment through mutual recognition of procedures. Article 6 requires that 'whenever possible, that the results of conformity assessment procedures in other Members are accepted, even when those procedures differ from their own, provided they are satisfied that those procedures offer an assurance of conformity.' Adoption of the Code is voluntary and currently lacks an enforcement mechanism. Efforts by governments to negotiate mutual recognition of conformity assessment procedures may

94. Trachtman, J.P. (2006) *Embedding Mutual Recognition at the WTO*. Tufts University.

therefore provide greater likelihood of reduced barriers than reliance only on the TBT, albeit with TBT's encouragement.

18.60 Trachtman⁹⁵ analyses how these WTO agreements uphold and encourage MRAs generally, arguing that 'mutual recognition at the WTO, as a type of liberalism, must be embedded in a process of governance that [includes] mutual recognition [and] can only take place to the extent of satisfactory essential harmonisation: to the extent that states can legitimately agree on an appropriate level of regulatory protection. This political process is necessary in order to establish an agreed minimum level of regulation.' Meanwhile, mutual recognition 'is not so much a rule of governance in the normal sense, but a rule of choice of governance': it thus requires trust, entailing 'an agreement to compromise local regulatory autonomy, by accepting that the exporting state regulation is 'good enough.'" MRAs can also allow the maintenance of 'safeguards' allowing states to protect against threats to public policy.

18.61 We have shown the areas where a US-UK FTA would be needed to ensure open trade, competitive markets and property rights protection. However, it is important to look at how feasible such an agreement would be.

95. *Ibid.*

19. HOW POSSIBLE IS A US-UK FTA?

- 19.1 The below is our assessment of the relative ease or difficulty of reaching agreement on each sector in the UK-US FTA, based on the existing political economies in each country. As an overarching theme, one of the challenges for the UK will be balancing its negotiations with the US with the demands of the EU in any parallel FTA, which could affect its ability to be flexible in some areas.
- 19.2 President Trump's statements on withdrawing from TTIP and TPP negotiations have been accompanied by a commitment to reducing the trade deficit. This does not necessarily mean that there is no potential for a US-UK trade agreement. First, Paul Ryan, US Republican Speaker of the House of Representatives, has recently reiterated the commitment to achieving a bilateral trade agreement between the US and the UK.⁹⁶ This was also accompanied by the statement that the US will also work closely with the EU to chart a path forward on TTIP. President Trump has also moved from the rhetoric of terminating NAFTA to renegotiation instead. These indicate that there is appetite in the US to continue with trade negotiations and agreements, including with the UK. The point is that by the yardstick the Trump administration uses to measure the relationship, the UK does not present the challenge that less developed or more distorted markets do.
- 19.3 Second, in terms of the statements on reducing the trade deficit, this would not necessarily be a barrier to greater trade with the UK. Interestingly, US and UK trade data show very different pictures of the trade relationship. The UK data for 2015 indicates a trade surplus in goods and services, with UK exports to the US greater than UK imports from the US by £39,318m.⁹⁷ The US trade data, however, indicates that the US had a trade surplus with the UK in terms of goods and services of \$12,008m in 2015.⁹⁸ Apart from highlighting the challenges with consistency in international trade data, this demonstrates that greater trade with the UK will not necessarily be incompatible with US stated objectives.
- 19.4 Finally, the Trump Administration has stated that it wants 'trade deals that work for all Americans'.⁹⁹ The focus is on supporting US manufacturing; the comparative advantage of trade for the UK is in services, particularly financial services, and so in any US-UK trade deal, the UK should not be seen as a direct competitive threat.
- 19.5 Our view of the potential ease of agreement across the specific areas, taking into complexity of subject matter, political will on both sides, against potential payoffs from agreement is illustrated in Figure 3, with specific discussion following.

FOOD AND AGRICULTURE

- 19.6 The challenges to an agreement on agricultural products may include the US seeking greater access even in products that the UK produces, such as dairy and meats. Further, any changes

96. <https://www.theguardian.com/us-news/2017/apr/19/paul-ryan-london-visit-us-uk-trade-agreement-brexit>

97. ONS, The Pink Book 2016

98. US Census Bureau and US Bureau of Economic Analysis, *US International Trade in Goods and Services*, February 2017

99. <https://www.whitehouse.gov/trade-deals-working-all-americans>

to required standards is likely to be opposed by consumer groups, as demonstrated by the public outcry and concerns about 'chlorinated chicken' and 'hormone-fed beef' accessing the UK market under an agreement with the US. While an agreement in this area may be relatively simple in terms of complexity of arrangements, it may be politically more difficult. However, to the extent that providing access on agricultural products to the US allows for agreement in other areas that are more important for UK trade, such as financial services, the potential payoffs are large.

GOVERNMENT PROCUREMENT

19.7 The new 'Buy American, Hire American' executive order is likely to make an agreement in this area more challenging, particularly if this leads the way for state governments to mandate similar requirements. The outcomes of the review of agencies and of FTAs in this context will provide useful guidance as to the potential use of this policy. The challenge will be with negotiating a special arrangement for the UK with respect to government procurement under BAA.

DEFENCE

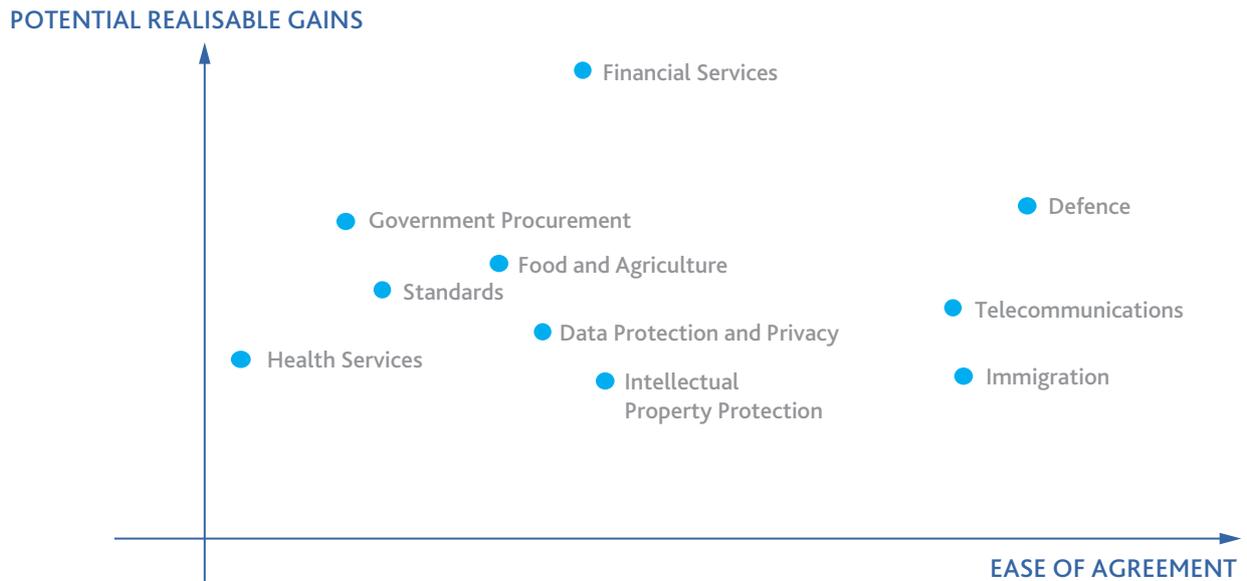
19.8 The political will of the parties is already aligned in this respect. As both parties already work closely together in the fields of defence and security, and have significant investment in defence industries in each other's territories, it is likely that agreement regarding defence will be straightforward.

INTELLECTUAL PROPERTY PROTECTION

19.9 The UK and the US will both want to implement strong intellectual property protection, and so this should not present challenges. The challenge rather will be in parallel arrangements with the EU. Strong IP rights will support investment. Any changes however, will also need to consider implications on different sector, and may need to be politically managed, such as through assuaging public concerns about the price of pharmaceuticals rising.

FINANCIAL SERVICES

19.10 Transatlantic trade in financial services is relatively free in terms of market access, but the challenge is in removing regulatory barriers, such as through mutual recognition. During the TTIP negotiations, the US was reluctant to include a forum for coordination on financial services regulation; while market access would be included, the US Trade Representative stated that regulatory cooperation was not a trade issue but rather should be discussed within existing other fora. As discussed in section 10, the agreement between SEC and ASIC is indicative that it is possible that the US would be willing to undertake a similar agreement with the UK on mutual recognition in certain areas of financial services.



Above: Figure 3
Relative ease and
payoffs from agreement
across specific key areas

TELECOMMUNICATIONS

19.11 Both parties will be keen to agree a competitive and free flow of digital services. The US has already shown initial willing to formalise agreement in this space by including provisions to this effect in the TPP. However, the extent to which the UK can be flexible in this area might be restricted by its membership of the Council of Europe Convention on Transfrontier Television and it will need to balance the benefits of retaining such existing commitments against the demands of the US.

DATA PROTECTION AND PRIVACY

19.12 From the UK perspective, UK lawmakers and consumers have certain expectations as to the use and protection of personal data that the UK may look to have addressed by the US in an FTA, which could also make the parallel negotiation with the EU less problematic.

For example, on 29 March 2017, the Trump administration overturned Federal Communications Commission (“FCC”) rules that required internet service providers (“ISPs”) to obtain consumers’ permission before sharing their browsing history with other companies. The FCC rules had not yet taken effect but would have required ISPs to obtain consumer consent before using their personal data (including precise geolocation, financial information, health information, children’s information and web browsing history for advertising and marketing).¹⁰⁰ This approach is unlikely to be acceptable to UK lawmakers and consumers, and, if no barriers to data transfer to the US from the UK are in place, could result in the EU imposing an absolute barrier to free flow of data to the UK.

HEALTH SERVICES

19.13 It is likely that the status quo regarding health care services will be maintained and not formally addressed in the US-UK FTA. The structure and ownership of the NHS is a politically sensitive topic. It was previously reported that the UK government had not ruled out more involvement by US companies in healthcare services as part of a UK-US trade deal,¹⁰¹ however any such discussions would be likely to delay the finalisation of a UK-US FTA. In any event, there has been little to no appetite from the Trump Administration in this respect.

IMMIGRATION

19.14 The Trump administration has been vocal in its defence of pursuing a tough immigration policy, however focus has previously centred on restricting immigration from certain countries for security reasons (not including the UK). In reality, discussions on this issue are likely to be straightforward as both parties will want to agree a mutually advantageous immigration policy with reciprocal rights that ensures a needs-based flow of skilled labour between the jurisdictions. Mutual flows of skilled workers can support greater knowledge exchange and innovation in both countries.

STANDARDS

19.15 Earlier sections have discussed in detail the challenges of MRA negotiations between the US and the EU. The challenge for the UK will be to develop a new conformity assessment system for standards that can support the creation of MRAs in new trading arrangements, including with the EU and the UK

19.16 While there will certainly be challenges in negotiating a deep trading agreement, the potential benefits are also high. UK ministers should start engaging with US counterparts immediately to discuss the opportunities for collaboration, and prioritising areas for negotiation and agreement.

¹⁰⁰. <http://www.reuters.com/article/us-usa-internet-trump-idUSKBN1752PR>

¹⁰¹. <http://www.independent.co.uk/news/uk/politics/theresa-may-donald-trump-nhs-us-trade-deal-brexite-torture-a7548156.html>

20. THE WIDER CONTEXT: RELATIONSHIP WITH OTHER US AGREEMENTS

- 20.1 President Trump signed an executive order withdrawing the US from the TPP on 23 January 2017. The ratification process for other countries to sign up to the TPP requires a minimum level of global trade to be covered. Had the US not withdrawn from the TPP, the TPP would have come into force two months after all the original signatories complete their own domestic ratification procedures. The second route for ratification under the TPP is that if at least six countries, which between them represent at least 85 percent of the total GDP of the original 12, have ratified it within two years, the agreement will come into effect. However, due to the extent of the US' GDP, if the US is not a party, the TPP cannot be ratified by the other parties unless the ratification process is changed by mutual agreement. The problem is that many of the countries offered concessions (such as Japan on Agriculture and Vietnam on SOEs) in order to have better access to the US market. If this is no longer on offer, the Agreement itself may make less sense to them. This will be a major stumbling block to the TPP. If the TPP were to survive in its current form, albeit without the US, then it would be possible for the UK to accede to it. That would not be a trivial exercise as it would involve a twelve country schedule negotiation, which would also implicate the UK's WTO rectification process which is moving forward at the same time. However, if the TPP's future is indeed very uncertain, its demise creates an opportunity for the UK. By bringing together like-minded countries whose original high level ambition gave rise to the TPP (such as New Zealand and Singapore whose initial bilateral led to the P4, then the P4 plus 1, then the TPP), these countries could develop a new Prosperity Zone characterised by open trade, competition on the merits as an organising principle and property rights protection, as outlined in 3.1. Note that if TPP were a live agreement, and if agreed with the other parties, on the day after the UK's exit date, the UK could join the TPP.

NAFTA RENEGOTIATION PROCESS

- 20.2 The North American Free Trade Agreement ("NAFTA") entered into force on the 1st of January, 1994. Today, it covers 14% of world trade, and 6 million American jobs depend on trade generated with Mexico under NAFTA; a further 8 million jobs depend on trade with Canada.¹⁰² Although a 2014 study found that the agreement costs 15,000 US jobs each year, each one of those jobs lost represents a \$450,000 increase in net welfare effects for the US.¹⁰³ NAFTA was the first free trade agreement to accord equal status to partners from the developed and developing world and pioneered advanced standards on IPR and investor-state dispute settlement ("ISDS"). NAFTA was also an early example of a strategic free trade agreement. One of the implicit goals of the negotiation was to prevent any regression on Mexican domestic liberalisation which had begun in the 1980s; it was also seen as a tool for the US to kick-start the slowing Uruguay Round in the WTO.

102. <https://www.foreignaffairs.com/articles/canada/2013-12-06/naftas-economic-upside>

103. <https://piie.com/sites/default/files/publications/pb/pb14-13.pdf>

- 20.3 In terms of international trade (especially for the US, Canada and Mexico), the two main legacies of NAFTA are: (1) including non-tariff barriers in free trade agreements in recognition of the fact that NTBs can have an equal if not greater dampening effect on trade than traditional tariff measures; and (2) pursuing free trade agreements in a strategic manner to guarantee the highest-possible standards. These principles can be seen most clearly in the TPP, which began as an FTA between New Zealand and Singapore in 2001 and grew to include advanced economies (e.g., the US, Japan, Canada) alongside small, distorted economies (e.g., Vietnam) in an agreement which tackled state-owned enterprises, competition and other regulatory issues traditionally considered to be the domain of domestic legislatures.
- 20.4 President Trump has pulled the US out of the TPP and formally notified Congress of his intention to renegotiate NAFTA with a view to its "modernization". The legal process and timeline associated with withdrawing from NAFTA are relatively straightforward, but it should be noted that the US has never formally withdrawn from a trade agreement before (and in only one instance, the US-Canada FTA, has it suspended a trade agreement). Article 22.05 of NAFTA states that "a Party may withdraw from this Agreement six months after it provides written notice of withdrawal to the other Parties".¹⁰⁴
- 20.5 As NAFTA is a congressional-executive agreement rather than a treaty (in the context of US law) and its provisions are not self-implementing, a congressional process for repealing the relevant provisions of NAFTA would be required.¹⁰⁵ Under the provisions of NAFTA, withdrawal (and therefore the end of trade preferences) could occur six months after notification; however, the Trade Act of 1974 (which was applied to NAFTA in the implementing legislation passed by Congress) stipulates that trade preferences must remain in effect until one year after withdrawal from a trade agreement, unless the president adjusts the rates/until the president recommends new rates to Congress, which he is required to do within sixty days of exiting an agreement. Again, it is worth noting that this stipulation (from Section 125, subsection (e)) has never undergone judicial scrutiny.¹⁰⁶
- 20.6 The legal process and timeline associated with renegotiating NAFTA are far more fluid. The Congressional Research Service has stated that it is 'likely' that a fully renegotiated deal would have to be approved by both houses of Congress.¹⁰⁷ Article 22.02 of NAFTA provides for the modification of the agreement but does not specify how modifications would/should enter into force. The President would have the authority to unilaterally enact certain changes relating to tariff lines or rules of origin, but his authority is less clear on more complex provisions including ISDS. A 90-day congressional consultation process is required before the US formally enters into a renegotiation of the agreement; this has now been commenced. A document released by the Mexican Foreign and Economic Ministries in late January 2017 suggested that consultations had begun simultaneously with a similar process in Mexico.
- 20.7 On 18 May 2017, USTR Robert Lighthizer wrote to Congress, triggering the NAFTA renegotiation process. This letter initiates a 90 day process of consultations, after which the US will open negotiations with Canada and Mexico. The letter sets out the USTR's key objectives for the renegotiation. Prior to the letter, there had been much speculation as to what that renegotiation would involve. It was not clear whether President Trump meant to withdraw the US from of NAFTA

104. <https://www.nafta-sec-alena.org/Home/Legal-Texts/North-American-Free-Trade-Agreement?mvid=1&secid=d5a8ba07-1fb2-4f28-88d0-a8eac08611a2>

105. <https://fas.org/sgp/crs/misc/97-896.pdf>

106. <https://fas.org/sgp/crs/misc/R44630.pdf>

107. <http://www.strtrade.com/news-publications-NAFTA-renegotiate-president-Congress-020117.html>

completely, or whether would seek to impose punitive tariffs on imports from Mexico. Instead, and contrary to much of the speculation, President Trump's trade envoy has signalled that the US will aim to modernise the NAFTA by adding provisions on regulatory practices, state-owned enterprises ("SOEs") and intellectual property rights (among other things). Many of these matters are dealt with extensively in the TPP, and it is likely that any new NAFTA provisions will be drawn from the provisions of the TPP in these areas.

- 20.8 Broadly these objectives, especially the provisions on SOEs and regulatory practices, are intended to deal with behind the border barriers to trade, regulatory issues and anti-competitive market distortions. These objectives have not been newly devised for this process, but represent an evolution of ideas to deal with the realities of trade in the 21st century.¹⁰⁸ These ideas were initially included in the US-Singapore agreement where provisions to deal with SOEs were added. There has been a gradual evolution of the SOE issue from a concern about the nature of ownership (the US-Singapore agreement contains a detailed annex which is focused on identifying what type of entity qualifies as an SOE) to a concern about the effect of the SOE on global trade if it benefits from state privileges and immunities that lead to an artificial reduction of cost. A NAFTA renegotiation could play a significant role in this area. Stronger measures in these areas which guarantee both free and fair trade are to be welcomed, and such changes would make it easier for the UK to come to an agreement with the US, and to even contemplate potential NAFTA accession in the future. It should be noted however that while there is currently bi-partisan support for a bilateral agreement between the UK and the US, it is not a given that there would be the same support for a UK NAFTA accession (or the necessary support from Canada and Mexico).
- 20.9 Although not specifically referenced in the letter, rules of origin dictating the percentage composition of a product required for it to qualify for preferential tariff rates will also be a likely topic of discussion. Any move to raise the percentage required to qualify under rules of origin would be designed to increase sourcing from the US, particularly for Mexican manufacturers; however, such a move would likely hurt US manufacturers more than their Mexican counterparts. Mexico has the option to trade at an average 2.5% tariff with the US under the non-preferential MFN rates and would therefore face little economic pressure to dramatically change its sourcing practices. Likewise, any further restrictions on government procurement (e.g., strengthened requirements for the Buy America programme) could be expected to bring equal retaliatory measures from the Mexican government. As major American firms have far greater economic ties with the Mexican government (e.g. Microsoft) than do their Mexican counterparts with the US government, this would seem doubly unwise for US taxpayers.
- 20.10 A host of **non-trade issues** could also be expected to feature prominently. The Trump administration has a particular interest in stemming the tide of illegal immigration, drug and arms trafficking from Central America through Mexico, and would probably demand further cooperation on these issues in exchange for continued free trade. **Investor-state dispute settlement** would also be a likely flashpoint, as it enjoys little domestic support or understanding in the US and Canada. The **environment and labour** side letters which accompanied the original agreement might well be revised or expanded. President Trump won an unexpected berth of support in the

¹⁰⁸. See *Trade Tools for the 21st Century* *ibid*

labour union-strongholds of Michigan, Pennsylvania, Ohio and Wisconsin on protectionist rhetoric; while he does not enjoy good relations with established labour (the AFL-CIO), he may well attempt to strengthen the labour side letter to win further favour with those voters. Similarly, President Trump has shown little interest in the environmental movement, but might use the environmental side letter to further restrict trade, especially in manufactured goods, on the basis that Mexican environmental standards are weaker than those in the US. He will at the same time be looking to weaken US environmental protections. Trump has already taken several steps to do this domestically. On 28 March 2017, Trump signed an executive order instructing US environmental regulators to make key changes to existing rules relating to the lowering of carbon emissions, including lifting a moratorium on federal coal leasing and removal of the requirement that federal officials consider the impact of climate change when making decisions.

- 20.11 Re-opening NAFTA presents some opportunities for Mexico and Canada. The US has many vulnerabilities in the area of behind the border barriers (see earlier sections and appendices). Access for all parties could be increased in several sectors, including but not limited to: maritime, ground transport, medical tourism, defence contracting, and antitrust standards. For example, the Jones Act restricts foreign-flagged vessels from delivering cargo to multiple US ports¹⁰⁹ and was carved out as an exemption in NAFTA; ground transportation as a cross-border service is also restricted, save in designated commercial zones near the border. These restrictions represent real costs to American, Mexican and Canadian consumers; one estimate puts the cost of the US-Mexico ground transport restrictions at \$400 million a year.¹¹⁰
- 20.12 One of the many things the Trump administration should consider is improving the existing trade adjustment assistance ("TAA"). Wage insurance provides a guaranteed income (some percentage of a worker's annual salary) for several years after their job is moved abroad; trade adjustment assistance more broadly provides retraining and relocation services. Wage insurance, while costly, might be an acceptable proposition if applied only to those workers who are 60 years of age or older, as this demographic is the least likely to be retrained and the least likely to find new gainful employment. However, TAA has historically not been very effective. In a study by the American University, Washington D.C.,¹¹¹ it was found that TAA participants earned 30 percent less on average than they made in their previous positions before entering the programme. In a comparison group made up of individuals that didn't receive TAA training or benefits, a reduction in wages was identified, but only by 9.4 percent. A further study by policy research firm Mathematica found the costs of TAA outweighed the benefits by nearly \$54,000 per participant.¹¹² Accordingly, any policy suggesting this alone as a way of solving trade concerns is unlikely to be effective.
- 20.13 Applying an ACMD-based metric to imports from Mexico might also allay American fears of unfair competition. Unlike the triggers for anti-dumping measures and counter-vailing duties, anti-competitive market distortions include all non-competitive benefits bestowed upon a firm or product, such as laws and regulations that eliminate or suppress competition, differential application of laws and regulations, activities of state owned enterprises and anti-competitive state aid and support.¹¹³ Operating a mechanism to address these matters in NAFTA would allow the US to impose tariffs on imports from Mexico and Canada where a domestic producer is able to

109. The Jones Act requires US-flagged carriers to conduct traffic and cargo operations between US ports.

110. <http://www.coha.org/us%E2%80%93mexico-nafta-transportation-agreement-imperiled/>

111. <http://w.american.edu/cas/economics/repec/amu/workingpapers/2008-12.pdf>

112. <https://www.mathematica-mpr.com/our-publications-and-findings/publications/the-benefits-and-costs-of-the-trade-adjustment-assistance-taa-program-under-the-2002-amendments>

113. As further identified and described by Shanker A Singham and Molly Kiniry in *Introduction to Anti-Competitive Market Distortions and the Distortions Index* (September 2016)

demonstrate that: i) they have suffered harm; ii) as a result of a distorting measure by the exporting country's government; iii) that has an anti-competitive effect in the relevant market.

- 20.14 In terms of the impact that the NAFTA renegotiation will have on the UK's trade negotiating prospects post-Brexit, most options are broadly positive. The complete implosion of NAFTA would make Canada and Mexico more open to a fully liberalised Prosperity Zone than they might be given the uncertainties of NAFTA. Any reduction in the scope of NAFTA leading to a loss in North American trade would also make Canada and especially Mexico more likely to seek out some form of hedge against what the US might do *vis a vis* NAFTA.
- 20.15 If the NAFTA renegotiation deals with the issue of ACMDs in a positive manner, then it is very likely that the NAFTA countries can accede to the emerging Prosperity Zone. Indeed, such a transition would be a great advantage for such an agreement.
- 20.16 Any NAFTA renegotiation would have to be approved by Congress, and Congressional approval of substantial changes to the NAFTA that would restrict trade and risk existing supply chains is unlikely.

US BORDER TAX PROPOSAL

- 20.17 House Speaker Paul Ryan and Ways and Means Chairman Kevin Brady have released a Blueprint for revising the US tax code which has received support from the Trump administration. It seeks to "fuel job creation and deliver opportunity for all Americans, simplify the broken tax code and make it fairer and less burdensome, and transform the broken IRS into an agency focused on customer service." Professor David Bradford's work on developing an X tax—a progressive VAT-model tax which could be used in the US—is the intellectual basis of this proposal. The proposed reforms include collapsing the current seven-tier bracket system for income tax into just three tax brackets. Under the new plan, income taxes will be levied at rates of 35 percent, 25 percent and 10 percent. In addition, the proposals include a reduced rate for small businesses and corporations.
- 20.18 Under this proposal, companies would be taxed at a rate of 20% on their cash flow in the US, minus the cost of labour, the cost of US goods, and the cost of services (the border adjustment applies only to goods, so all services would remain deductible from the tax base). This is functionally a VAT tax of the consumption type, fundamentally focused on determining cash flow. It is designed to deter companies currently operating in the US from leaving for lower-tax or lower-cost markets and then exporting their products back to the US. It would correct many of the current inconsistencies in the US tax code, including the fact that labour is taxed twice, and that foreign investment is essentially subsidised by the ability to easily invest abroad and repatriate revenues at low tax rates. It would discourage consumption and incentivise saving and investment at the personal and corporate levels.
- 20.19 It is important to note that this Blueprint is still in draft form and subject to further revision in the House before it goes to the Senate, where Sen. Ron Wyden of Oregon, the ranking member on the Senate Finance Committee has already expressed scepticism (Sen. Wyden's home state is also the headquarters of Nike, a company highly dependent on the ability to cheaply import foreign-made goods). Sen. Ben Cardin of Maryland has begun drafting a response to Speaker Ryan's

CURRENT US SYSTEM	PROPOSED US TAX SYSTEM (IN CONGRESS)
<ul style="list-style-type: none"> • Income tax for corporations and individuals • Corporate income is taxed at 35% • Many personal and corporate deductions exist, including carried interest • A universal taxation system; companies and individuals are taxed on their income at home and abroad • Labour is effectively taxed twice—first for corporations, and again for individuals 	<ul style="list-style-type: none"> • Eliminates corporate and personal income tax • A true territorial tax system • Replaces corporate income tax with a border-adjusted tax of 20% • The border-adjusted tax will be based on cash flow with labour costs deducted • Eliminates carried interest • Simplifies/reduces many exemptions currently in place

proposal, which more closely resembles a credit and invoice VAT system. It is likely that in the conference negotiations between House Ways and Means and Senate Finance, a more moderate proposal will be brought forward. It is also worth noting that the White House may press for further amendments—President Trump has historically expressed a preference for simple tariff barriers, stating that this proposal is “too complicated”.

20.20 A proposal along these lines could impact US-UK trade, and a potential US-UK FTA, in a variety of ways. First, the Double Taxation Agreement of 2002 is predicated in part on the US corporate and personal income tax system, and so some modification of the Agreement will likely be required (failing that, ‘income tax’ will have to be left on the Federal Register in the US in a nominal way so as to keep the relevant provisions of the Agreement valid). Second, it would disadvantage goods exports from Britain to the US. The US is the UK’s biggest export market (£47 billion in goods, £53 billion in services, in 2015). Britain’s services exports would not be affected by this proposal. Third, and perhaps more significantly, this new tax code would remove the current incentives for foreign investment by US corporates solely driven by tax reasons. The UK is the largest beneficiary of US FDI, and would likely suffer a cash crunch under this new system. A sudden, sharp reduction in FDI from the US could systemically increase the cost of doing business across the UK.

20.21 At the time of writing it this proposal seems to have lost favour with the White House, and has been widely opposed by import-reliant retailers (though welcomed by exporters), but is still being supported by Brady and Ryan,^{113a} so may progress in some form. Even if this reform is abandoned, issues on taxation will remain, and HM Treasury should begin conducting conversations with the US Treasury Department to scope out the possible implications of this Blueprint on the Double Tax Agreement, and express the interests of British industry in maintaining the free flow of goods, services and investment across the Atlantic. This would likely be a more productive route for achieving HMG’s goals on international tax policy than continuing the Base Erosion and Profit Shifting (“BEPS”) talks in the OECD. There is palpable hostility in the US treasury regarding the UK’s role in BEPS. A shift in focus by the UK would be warmly received in Washington.

113a. <https://www.bloomberg.com/politics/articles/2017-05-23/house-chief-tax-writer-signals-openness-to-gop-plan-alternatives>

21. THE WIDER CONTEXT: UK'S SIMULTANEOUS NEGOTIATIONS WITH US AND EU

- 21.1 The fact that the UK will be simultaneously negotiating with the UK and EU presents opportunities and challenges. We have summarised the opportunities and challenges below.

OPPORTUNITY

- 21.2 In many areas of law and regulation the UK sits between the US and EU. Negotiating with both parties at the same time means that the UK can act as a bridge between the US and EU in certain key areas. For example, the UK has a commitment to animal welfare which it would wish to continue to have enshrined in its regulatory system, and such an "ask" would be a difficult issue to consider in a US-UK agreement. However, the UK may be prepared to give on some of the difficult SPS issues in poultry and beef as long as animal welfare issues were properly addressed in the agreement, particularly with respect to specific hormones such as ractopamine. Such an outcome would ease the difficult agricultural issues in an UK-EU agreement.

CHALLENGES

- 21.3 The specific challenges associated with the UK negotiating jointly with the EU and the US are obvious. In areas where the US and EU regulate in very different ways, and it may not be possible in certain cases to have an agreement that works for both parties and enables a single supply chain across the US-UK-EU region. Too much divergence between US/UK regulatory system and the EU regulatory system will make it difficult for UK entities to trade simultaneously with the US and the EU, unless they produce separately for both markets, and sometimes it is simply not possible to service both markets due to directly conflicting SPS measures, for example. For example, in financial services, the UK-EU arrangements will start from a point of regulatory convergence. However, the US-UK agreement may drive towards principles-based, pro-competitive regulation and (together with the UK's domestic concerns) therefore increase the possibility of regulatory divergence between the UK and EU. Managing this divergence will be one of the great challenges for coordinating across both of these agreements. There are a number of other specific areas where challenges arise.

DATA AND PRIVACY ISSUES

21.4 Other countries, notably the Swiss have had to manage these divergences and the Swiss approach is to adopt its own version of GDPR which it hopes will be compatible with the rules of the EEA. The Swiss model of the GDPR has the following key differences:

For example, the Swiss draft DPA is less strict in the following areas:

- a) Consent requirements (GDPR says consent cannot be bundled with other issues).
- b) Data coverage is less
- c) More information to be provided to data subjects for GDPR
- d) Under GDPR, no-EU processors of data must appoint an EU based processor no matter how minor their data processing role actually is.
- e) DPA is generally less prescriptive than the requirements of GDPR
- f) DPA fines are much lower (GDPR fines are up to 4% of annual turnover).

The question is whether the Commission will accept the Swiss DPA as ensuring adequate protection for EU citizens' data, and maintains Switzerland's position on its approved whitelist, allowing transfer of personal data to Switzerland without further safeguards. This negotiation will indicate the room for manoeuvre of the US and UK in their agreements.

FINANCIAL SERVICES

21.5 The simultaneous negotiations between the US and EU present serious issues in financial services. In order to ensure that UK firms can continue to transact business in the EEA without being locally licensed and supervised, there will have to be some sort of mutual recognition and ongoing co-ordination of regulation, especially prudential regulation. We set this out in our paper *A New UK/EU Relationship in Financial Services—a Bilateral Regulatory Partnership*.¹¹⁴ The question is whether this can be extended to include the US and other countries. If dual regulation systems are also governed by principles that allow the regulation and supervision of financial services providers of one jurisdiction to be recognised in the other, subject to compliance with international and other agreed parameters, and the parties to the US-UK agreement agree to work cooperatively in the international sphere to ensure that global standards reflect consumer welfare enhancing regulation, this will itself lead to greater levels of innovation. International financial services institutions will want to operate in such environments and these principles will also be important for consumers of those services.

21.6 Financial centres such as Singapore, Hong Kong, London, New York and Zurich have an interest in a common approach which will maximise consumer welfare, and thus innovation and wealth creation.

¹¹⁴ <http://www.li.com/activities/publications>

22. CONCLUSION

- 22.1 We recommend that any agreement between the UK and the US should be comprehensive and deal with as many of the historic demands of both sides as possible. There is a temptation on both sides for a “quick win” and a political agreement which will benefit the UK in its negotiations with the EU. This temptation should be resisted. There are real gains for both the UK and the US in a comprehensive free trade agreement. There are also advantages to negotiating with the US and the EU at the same time, which will be necessary for the UK to act as a bridge between the two. While this “triangulation” also presents challenges, a wise negotiator will seek to maximise the opportunities whilst realistically tackling the challenges.

APPENDIX 1

US Barriers

	US BARRIERS	EFFECT
Agriculture	Agricultural Adjustment Act (1938), Agriculture Act (1949), Commodity Credit Corporation Charter Act (1948) and the Farm Act (2014) form the basis of US agricultural subsidies	The extensive subsidisation of US agriculture distorts the market in favour of domestic producers and certain crops, adding an extra barrier for foreign producers to export to the US market.
	Special Agricultural Safeguard measures across 188 tariff lines	These safeguard measures allow the US to impose additional tariffs for the related products if import prices dip below a certain point—the US has itself advocated for the removal of agricultural safeguard measures in the WTO.
	Tariff rate quotas on 44 lines, including: dairy, beef, citrus, sugar, chocolate, olives, tobacco, cotton, and animal feed	TRQs allow a given quantity of a good to be imported at one tariff level which then rises when the quota is 'used up'; these are market distorting measures, especially when administered on a first-come, first-served basis, which encourages frontloading imports.
	Agricultural product fees on imports via Animal and Plant Health Inspection Service ("APHIS"), authorised under Section 2509 of the Food, Agriculture, Conservation, and Trade Act of 1990	Agricultural quarantine fees must be paid to APHIS for inspecting every shipment of agricultural/veterinary goods entering the United States; as of 2017, these fees were \$825 per commercial cargo vessel and \$225 per commercial aircraft.
	Excise taxes on tobacco and alcohol products may be levied at the federal, state or local municipal level	Three levels of government can and do levy 'sin' taxes on alcohol and tobacco products; at the federal level, this is roughly \$0.05 per can of beer, \$0.31 per bottle of wine, \$2.14 per handle of hard spirits, and \$2.11 per pack of cigarettes. Additional taxes are levied at the state and local level.
	The Department of the Interior maintains import and export licenses for fish and wildlife	These licences cost \$100 per annum and require a US agent for foreign exporters, as well as a record-keeper responsible for maintaining the licence records for five years after the expiration of the licence.
	Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (80 FR 55907)	This regulation requires a written safety plan which analyses foreseeable hazards, implements preventative controls, monitoring, product verification through third party labs, and strict control of supply chains—these steps all represent significant additional costs for anyone operating a farm or food processing plant in the US.
	Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP Rule) (80 FR 74225)	US owners or consignees of imported food and/or the US agency or representative of the foreign owner of consignee are responsible for determining known or foreseeable hazards, evaluating the risk of imported food products, and conducting supplier verification activities through application of a written plan. Violations can lead to prosecution.
	Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule) (80 FR 74353)	These regulations place strict requirements on agricultural water and soil quality permitted in the growing of produce, and also on worker training and equipment/buildings safety.
	Mitigation Strategies to Protect Food Against Intentional Adulteration (Intentional Adulteration Rule) (81 FR 34165)	This regulation is designed to prevent disgruntled employees, competitors or domestic terrorists from negatively impacting the food supply. The Intentional Adulteration Rule requires firms to identify each 'actionable step' at which they could implement safety measures against intentional adulteration, and then implement them. These are left to the discretion of the firm, except for bulk liquid receiving/storing, liquid storage/handling, secondary ingredient handling and mixing activities, all of which require the implementation of safety precautions.

	US BARRIERS	EFFECT
Agriculture <i>continued</i>	Sanitary Transportation of Human and Animal Food (Sanitary Transportation Rule) (81 FR 20091)	This rule applies to shippers, receivers, loaders and carriers who handle food within the US, including those in foreign countries who intend to ship food to the US; it specifies certain requirements in the design of transportation equipment and its maintenance, including temperature controls, cross-contamination prevention and separation of raw/ready-to-eat food, as well as training of carrier personnel and maintenance of extensive records.
	Information Required in Prior Notice of Imported Food (78 FR 32359), under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	Advance notice of import shipments of food must be given to the FDA and GBP; this can be provided through two channels but must be submitted no more than 15 days out from shipment for PNSI and 30 days out from shipment for ABI/ACS. If shipment of the same food has been refused in another country, the importer must notify the FDA.
	FSIS of DOA maintains a positive list for the import of certain livestock products.	Of the four nations, only England and Northern Ireland are certified to export pork to the US; beef and poultry products (including eggs) require further verification, including on-site inspection. ¹¹⁵
	Sugar program (price supports and supply control) under the Farm Bill of 1990	Sugar production and processing are heavily subsidised in the US, leading to diminished market access for foreign competitors operating at world prices. Producers are guaranteed minimum prices at which the USDA will buy their product (\$18.75 per pound of raw cane sugar and \$24.09 per pound of refined beet sugar). 85% of domestic sugar demand must be met by domestic suppliers; the USDA annually allocates a share of the expected market to sugar producers. Additionally, imports are managed through TRQs—these allocations are based on the domestic market from 1975—1981 and is often criticised for not reflecting the current market conditions.
	Margin Protection Program for Dairy Producers; Dairy Product Donation Program, and Federal Milk Marketing Orders (subsidised insurance for margins, market support measures, etc)	The MPP covers producers by paying them when dairy margins dip below a given margin; coverage of \$4 per hundredweight is free, and coverage at 50-cent increments up to \$8 per hundredweight is available for a premium. Producers have the option to 'protect' between 25 and 90% of their production history. Under the Dairy Product Donation Program, the USDA is required to purchase dairy products for donation to food banks and individuals on food assistance programs if margins fall below \$4 per hundredweight for two consecutive months.
Defence	International Traffic in Arms Regulation, 22 USC 2778 of the Arms Export Control Act and Executive Order 13637	ITAR is a set of deeply comprehensive and wide-ranging set of regulations originally designed to match the export arms control regulations in place in the Eastern Bloc of the Soviet Union. Since 1999, it has been managed by the State Department. Manufacturers, exporters and brokers of defence articles, services, or related technical data must register with the State Department (at a cost of \$2,250 per annum); registration allows the designee to then apply for export licences. Retransfer (the foreign buyer selling the article to another foreign buyer) is very strictly prohibited unless included in the initial authorisation. The State Department aggressively pursues violations of ITAR; famously fining ITT \$100 million for retransfer of night vision technology; major defence contractors including Northrup Grumman, Boeing and Lockheed Martin have also faced stiff penalties. ITAR represents a serious and prohibitive cost for global defence trade.

¹¹⁵ https://www.fsis.usda.gov/wps/wcm/connect/4872809d-90c6-4fa6-a2a8-baa77f48e9af/Countries_Products_Eligible_for_Export.pdf?MOD=AJPERES

	US BARRIERS	EFFECT
Financial Services	Dodd-Frank Wall Street Reform and Protection Act of 2010 (PL 111-203,H.R. 4173)	Dodd-Frank was the primary response of the US government to the financial crisis of 2008. It establishes the Financial Stability Oversight Council and the Office of Financial Research in the Treasury Department to monitor systemic risk in the financial services sector, with the right to place nonbank companies under the supervision of the Federal Reserve, to issue legally binding 'suggestions' to the relevant supervisory authority as regards certain activities, to subpoena witnesses, and to require any bank or nonbank institution to provide certified financial reports; it allows the Treasury to label certain institutions as 'systemically important financial institutions', which automatically places them under a stricter set of regulations; it requires certain institutions to create 'living wills'; it expands the number and type of institutions under 'liquidation authority' for the Federal Deposit Insurance Corporation; to levy 'assessment fees' to cover the costs of the Orderly Liquidation Fund; it requires hedge fund managers and private wealth managers to register under the Investment Advisers Act of 1940; it establishes the Federal Insurance Office, which is responsible for monitoring the industry, including the extent to which traditionally underserved and minority groups are able to access the insurance market, and implementing the Terrorism Insurance Program; it establishes the Volcker Rule by amending the Bank Holding Company Act of 1956, thereby limiting the right of banking entities to own more than 3% of the total ownership interest of a hedge fund and/or to have investments in a hedge fund which exceed 3% of the value of their Tier 1 capital; it requires that derivative swaps be cleared through exchanges; it repeals the exemptions which were given to derivatives swaps under the Gramm-Leach-Bliley Act; it enhances the role of the Federal Reserve in supervising the activities of systemically important institutions; and it gives increased power to the Securities and Exchanges Commission, among other provisions. The Dodd-Frank Act has dramatically altered the landscape of financial services in the US and taken measures which, while designed to protect the public and the industry itself, ultimately limit profitability.
	International Banking Act of 1978—governs the operations of foreign banks in the US	This Act brings all American branches of foreign banks under American jurisdiction, with the rights (FDIC insurance) and responsibilities (capital adequacy requirements and auditing schedules) as domestic banks.
	Securities Exchange Act of 1934	This Act established the Securities and Exchange Commission and regulates the secondary trading of securities, which represents a market worth trillions of dollars annually.
	Gramm-Leach-Bliley Act (Financial Services Modernization) of 1999—regulates the consolidated financial sector	The GLBA repealed the provisions of Glass-Steagall relating to combinations of investment/commercial banks and investment companies to allow further consolidation in the market; it also established privacy provisions which must be given to every customer to allow them to opt-out of third-party information sharing.
	Bank Holding Company Act of 1956	This Act regulates US banks affiliating with other financial services companies by setting up a bank holding company; it specifies that the Federal Reserve Board of Governors must approve the establishment of bank holding companies and banned interstate competition amongst bank holding companies. Much of this Act was subsequently repealed by Riegle-Neal and Gramm-Leach-Bliley.

	US BARRIERS	EFFECT
Financial Services <i>continued</i>	Riegle-Neal Interstate Banking and Branching Act of 1994—regulates branching by merger	This Act repealed portions of the Bank Holding Company Act to increase the competitiveness of banks operating on a federal charter to match that of banks operating on a state charter. It mandated review of a bank's performance on Community Reinvestment Act compliance before expansion could be authorised.
	Investment Company Act of 1940	This Act regulates conflicts of interest by requiring disclosure of material details and places restrictions on certain mutual fund activities, including short-selling. It is used primarily as a regulatory vehicle for the Securities and Exchanges Commission, whose powers it broadens.
	Investment Advisers Act of 1940	This Act requires investment advisers of every stripe to register with the SEC; it prohibits advisers from profiting from market activity caused by their advice to clients and gives them a fiduciary duty to their clients.
	Sarbanes-Oxley Act of 2002	This Act establishes and reinforces the responsibilities of public company boards, management and accounting firms. It establishes the Public Company Accounting Oversight Board and requires enhanced disclosure of financial transactions. It also increases the criminal and civil penalties for white collar crime and makes the CEO responsible for the company tax return.
Fisheries	Magnuson-Stevens Fishery Conservation and Management Act	This Act maintains a positive list of countries whose fishing practices are acceptable and eligible for export to the US; the UK is on this list.
	Subsidy programs: Columbia River Fishery Development Program, Sea Grant College Program, Saltonstall-Kennedy Grant Program: Fisheries R&D, Fisheries Finance Program	As with broader agricultural subsidy programs, these artificially lower the prices of domestic suppliers and inhibit the ability of foreign fish to compete in the US market.
Government Procurement	Only 37 states and the federal government are signatories to the GPA	This means that any municipal contracts are not subject to the GPA, thereby reducing market access for foreign firms. Furthermore, the Buy American Act is excluded from the GPA's coverage. GPA thresholds vary by country and are assigned on a reciprocal basis through free trade agreements.
	Buy American Act (1933), Trade Agreements Act (1977, which provides for waivers to the BAA), Federal Property and Administrative Services Act (1949), Competition in Contracting Act (1984), Federal Acquisition Streamlining Act (1994), and the Services Acquisition Reform Act	These Acts require the federal government to 'prefer' domestic goods and companies when making purchases—this extends to third party purchasing made with federal funding, e.g. the construction of state highways. Exceptions from the BAA are granted under certain circumstances; one of these circumstances is proof that use of a domestic supplier would yield an 'unreasonable' price; this is defined as 6% more than an international supplier generally, 12% more if a small business is concerned, and 50% more for any purchases for the DOD.
Insurance	McCarran-Ferguson Act of 1945 (US Code Title 15, Chapter 20)	This Act states that regulation of the insurance sector should take place at the state level, effectively creating a 50-state market which is difficult for foreign competitors to break into. The GLB specifies 13 areas of state insurance regulation that may not be pre-empted by federal law

	US BARRIERS	EFFECT
Investment	FINSA/CFIUS	<p>Officially, CFIUS has 30 days to conduct a review, 45 days to conduct an investigation, and 15 days for the President to take a decision. Unofficially, an 'informal' stage has become part of the de facto functioning of CFIUS; this is of an unspecified length of time and allows the firms party to CFIUS review and CFIUS staff to identify potential issues with a filing and restructure transactions to address national security issues. Firms participating in transactions which may raise national security issues (normally relating to foreign investment/a foreign buyer) may voluntarily submit a CFIUS filing; CFIUS may also 'request' a filing.¹¹⁶ If a 'request' is ignored, CFIUS may legally require a filing. If CFIUS reviews a transaction for which no notification was filed and finds that the transaction threatens national security, it has the authority to 'unwind' that transaction. Such a decision would not be subject to judicial review. True greenfield investments are the only transactions outside of CFIUS' scope.</p> <p>An amendment of the current law would need to be approved by both houses of Congress; any easing of the CFIUS process would likely face opposition from a body which has historically demanded more control over foreign investment in the United States, not less (see the case of Dubai Ports World). The 'easiest' case would likely be for fully private, fully British-owned firms which have already undergone national security vetting of some kind in the US (under the US-UK Defense Trade Cooperation Treaty, for example).</p>
Maritime	Merchant Marine Act of 1920/Jones Act (PL 66-261)	The Jones Act regulates maritime commerce in the US; its primary impact is to require that all goods transported via water between US ports (including US territories) be carried on ships flying the US flag, that were built in the US, and owned/operated/crewed by Americans.
Telecoms	Telecommunications Act of 1996	This Act attempted to correct many of the anti-competitive features of the Communications Act of 1934. It maintains the Universal Service obligation; includes the internet in broadcasting/spectrum allotment; allows cross-ownership in media; and forces incumbents to make access to their networks available at wholesale rates.
	Communications Act of 1934 as amended by the Telecommunications Act of 1996	This Act created the Federal Communications Commission and delegated the regulation of interstate telephone services to the FCC. The way in which this Act regulated new technologies prevented new entrants to the market and effectively created monopolies.
	Open Internet Order (commonly known as the FCC net neutrality decision)	The Open Internet Order makes 'net neutrality' the official policy of the United States—that is to say, that all internet traffic is treated equally. It forces internet service providers to disclose their network management practices and performance statistics; does not allow ISOs to block lawful content or applications; and forbids unreasonable discrimination against certain types of internet traffic.

116. http://www.jonesday.com/common_misconceptions_regarding_cfius/

UK Barriers

	UK BARRIERS	EFFECT
Agriculture	Nutritional labelling—EU framework regulation 1169/2011	This regulation regulates the display of product information on product packaging and online stores ostensibly to provide consumers with information related to nutrition, ingredients and allergens.
	GMOs—Directive 2015/412, Member State opt-out provision	Member states (including regional governments) are given the option of deciding whether or not GMO crops should be allowed to be grown in their territory—nineteen member states have opted out for all or part of their territories.
	GMOs—Directive 2001/18/EC	Cultivation of GMOs requires authorisation from the relevant national authority and the Commission; if one or more Member States raises objections, the European Food Safety Agency must submit a risk assessment. GMOs must be labelled as such, monitored, and recorded in a register.
	Fertiliser—Council Regulation 2003/2003	This regulation defines the composition, marking, labelling, packaging and identification requirements for designation as 'EC fertilisers', which can be freely sold and used across the EU. Laboratories capable of determining conformity with these standards are designated at the national level.
	Pesticides—Commission Regulation 1107/2009; Commission Regulation 396/2005; Commission Implementing Regulation 540/2011	Pesticides are broadly covered by REACH regulation; there is a very long process for the approval of active substances in pesticides (2.5 to 3.5 years in theory, in practice much longer).
	Hormones and beta agonists—Directive 96/22/EC, as amended by Directive 2003/74/EC	The EU effectively bans the import of hormone-treated beef beyond what has been considered 'sound science' in the WTO.
	Pathogen reduction treatments—EC Regulation 853/2004	This regulation bans the import of meat which has been subjected to any pathogen reduction treatment other than water—this primarily affects chlorine-washed poultry products from the US.
	Export certification—Council Regulation 338/97	This regulation defines the conditions under which import, export and trade of wild flora and fauna can occur. It creates and mandates import and export permits, re-export certificates, import notifications and internal trade certificates required for trade in the hundreds of plant species listed in the Appendix to this regulation.
	Somatic cell count (milk)—EC Regulation 853/2004, Annex III Section IX	This regulation defines somatic cell count as an indication of milk quality and specifies what amounts of SCC may be present for milk to be sold on the EU market; an SCC of 200,000 per ml of milk means that a cow is likely to have at least one infected udder; 300,000 or higher means that a cow is likely to have a significant infection, and 400,000 or higher means that milk from this cow is unfit for human consumption. The limit in the US is 750,000.
	Citrus canker—Council Directive 2000/29/EC	Fruit bound for EU export is subject to inspection in the grove pre-harvest and post-harvest inspection before shipping. If any canker lesions are found on a piece of fruit bound for export, the entire production block is disqualified for export to the EU.
EU framework regulation 1151/2012	This regulation is broadly focused on 'inclusive growth' in the European agricultural market through 2020. It sets out the framework for quality schemes and protected designation of origin and protected geographical indication schemes. By their very definition, these schemes exclude foreign competition from the EU market for products under these designations (e.g., feta, parma ham, Herefordshire cider, etc.).	

	UK BARRIERS	EFFECT
Agriculture <i>continued</i>	Wine traditional terms—Council Regulation 479/08; Commission Regulation 607/09; Commission Regulation 1308/2013	These regulations set up the support programmes, trade regulations, quality controls and production limits for wine production in the EU. It also creates the vineyard register, compulsory declarations on harvest, production and transport, and records on transport and wine-making processes. It lays out the 'authorised wine making practices', acceptable levels of sulphur dioxide and volatile acidity, lays out the traditional terms/PGIs/PDOs associated with wine and disallows coupage of third country grapes in the EU.
	Whisky aging requirements—EC Regulation 110/2008, Annex II Category 2; Scotch Whisky Regulations 2009	The Commission has started discussions with the member states on a possible simplification of wine labelling set out in Regulation 607/2009, but appears to be facing resistance to any changes that would lessen the protection of traditional terms.
	Trucks: Maximum Authorised Dimensions—Directive 2015/719/EU	These regulations mandate aging requirements for 'whisky/whiskey' products to be sold on the EU market; US whiskey manufacturers often age their whiskey for less time in a different type of barrel which produces similar results. These regulations exist to protect the domestic Scotch Whisky association.
Automobiles	Emissions—Directive 2007/46/EC, Euro 5 and 6 Regulation 715/2007/EC, Regulation 692/2008/EC, Regulation (EU) 2016/427, Regulation 595/2009/EC, Regulation (EU) 582/2011	This directive favours trucks manufactured in the EU to this standard over those manufactured in the US; there is no measurable safety differential between the two types of truck.
	Airbus subsidies	The EU maintains strict regulations designed to curb carbon dioxide emissions. The suite of regulations provides a legal framework for the type approval of cars, vans, trucks, buses and coaches and set the emission limits for cars for regulated pollutants, in particular nitrogen oxides for light and heavy-duty vehicles.
Aviation	REACH—European Parliament and Council Regulation 1907/2006	Airbus receives roughly £8 billion a year in subsidies from the European Union, despite being required by the WTO to cut these subsidies.
Chemicals	Renewable Energy Directive—2009/28/EC	REACH is the extraordinarily complex and wide-ranging set of regulations governing the production, sale and trade of chemicals in the EU. Broadly speaking, it requires registration and authorisation of chemicals used in the EU; disclosure of chemicals found in a given product within 45 days of a consumer request; that tests be conducted on vertebrates before market access is granted (and that the results of these tests be sold for a 'reasonable' price); and restricts the registration of chemicals to representatives based in EU countries.
Energy	Uranium—The Corfu Declaration (1994)	This directive mandates certain levels of renewable energy usage in the EU; this has been set at 20% by 2020, with a further reduction of carbon dioxide emissions by 20% and to achieve energy savings of 20%. The UK remains significantly behind these targets.
	Financial Services and Markets Act 2000, Regulated Activities Order and Markets in Financial Investments Regulation ("MiFIR")	The Commission presented a new Renewable Energy Directive ("RED II") for the period 2020–2030 as part of a comprehensive "Winter Energy Package" of legislative proposals which includes initiatives on bioenergy sustainability (liquid biofuels and biomass). RED II was adopted by the Commission on November 30, 2016.
Financial Services	Solvency II	This declaration effectively shields 80% of the European uranium market from import competition.

	UK BARRIERS	EFFECT
Financial Services <i>continued</i>	Alternative Investment Fund Managers Directive 2011/61/EU ("AIFMD")	Requires that businesses must be authorised by the Financial Conduct Authority in the UK to provide certain financial and investment services. MiFIR sets out a number of additional reporting requirements in relation to the disclosure of trade data to the public and competent authorities (to come into effect in January 2018).
	European Market Infrastructure Regulation ("EMIR")	Solvency II was primarily introduced by the EU to regulate the amount of capital that EU insurance companies must hold to reduce the risk of insolvency and to harmonise the EU insurance market. It includes quantitative requirements (for example, the amount of capital an insurer should hold), requirements for the governance and risk management of insurers, as well as for the effective supervision of insurers and disclosure and transparency requirements.
	Fish products labelling—Commission Regulation 1379/2013	AIFMD imposes requirements on Alternative Investment Fund Managers ("AIFMs"), including authorisation by a home state regulator, strict operating conditions, transparency requirements. The directive arguably puts non-EU funds at a disadvantage as EU funds managed by EU managers may be marketed across the EU under the AIFMD passport, which is not available for non-EU managers.
Fisheries	EU Utilities Directive	EMIR includes strict rules relating to OTC derivatives, central counterparties and trade repositories. EMIR includes detailed reporting requirements, rules on clearing and monitoring requirements by market participants.
Government Procurement	Data Protection Directive 1995/46—to be replaced by the General Data Protection Regulation and range of measures on privacy and e-commerce	This regulation requires that all fish products be labelled to show the commercial name of the species, their country of origin and method of production.
Information Services	Directive on Audiovisual Media Services	These directives specify the procurement provisions in place for public utilities companies in the EU. Specifically, it calls for non-discrimination, equal treatment, proportionality, transparency and mutual recognition in awarding government procurement contracts in this sector. EU companies are given preference in bids concerning water, energy, postal services and urban transport; moreover, if the majority of a bid's goods come from outside the EU, they can be rejected.
Media	Transport Fuel: Fuel Quality Directive 2009/30/EC	The EU maintains strict rules for the sharing and protection of personal data. This includes the right to be forgotten, mandatory requests for the usage of cookies on websites, etc.
Road & Rail	Single market in telecommunications—TSM	The AVMS requires member states to comply with certain content requirements in exchange for the ability to automatically distribute their country's content to other EU member states; this includes a requirement to reserve a certain amount of airtime for 'European works'.
Telecoms	Conformity assessment framework—Commission Regulation 765/2008 and Decision 768/2008	This directive gives specification to petrol and diesel products which can be sold in the EU and requires suppliers to reduce the carbon-intensity of fuels used for road transport.
Standards		The TSM covers all aspects of telecommunications, including broadband, radio, television and phone networks. Historically, it has been difficult for US telecoms operators to penetrate the EU telecoms market, due to the existing dominance of national incumbent operators and the presence of multiple localised anti-competitive barriers to entry in each Member State.
		These regulations provide a legal framework for accreditation services across Europe, including testing facilities, inspection services, conformity assessments of products, management systems or persons, and emissions verifiers for carbon targets.

APPENDIX 2

Telecommunications Equipment

RELEVANT REGULATION	
EC	USA
<p>Directive 98/13/EC of the European Parliament and of the Council of 12 February 1998 relating to telecommunications terminal equipment and satellite earth station equipment, including the mutual recognition of their conformity, and interpretation thereof;</p>	<p>Communications Act of 1934, as amended by the Telecommunication Act of 1996, (Title 47 of the United States Code).</p> <p>The US regulatory and administrative provisions in respect of telecommunication equipment, including 47 CFR Part 68, and FCC interpretation thereof;</p>
<p>(The Parties recognise that the Handbook on the implementation of Directive 98/13/EC (ADLNB and ACTE approved), provides useful guidelines for the implementation of conformity assessment procedures falling under this Directive.);</p> <p>Commission Decisions (“CTRs”) established under Directive 98/13/EC;</p> <p>The EC Member States’ legislation and regulations in respect of:</p> <ul style="list-style-type: none"> (a) non-harmonised analogue connection to the public telecommunications network; b) non-harmonised radio transmitters for which there is a civilian equipment authorisation requirement. 	<p>(The Parties recognise that the FCC Form 730 Application Guide provides useful guidelines for the implementation of conformity assessment procedures for telecommunication terminal equipment falling within these regulations.);</p> <p>The US regulatory and administrative provisions in respect of all radio transmitters subject to an equipment authorisation requirement. A non-exclusive list of FCC regulations are contained in Section II.</p>

AFFECTED PRODUCTS	
EC	USA
<p>The following equipment categories are included:</p> <ul style="list-style-type: none"> • ISDN Basic Rate Access • ISDN Primary Rate Access • ISDN Telephony • X21/V.24/V.35 Access • X25 Access • PSTN Non-Voice • PSTN Voice Band (Analog) • ONP Leased Line Terminal types: <ul style="list-style-type: none"> • 64 kbits/sec • 2048 kbits/sec unstructured • 2048 kbits/sec structured • 4 Mbits/sec access • 140 Mbits/sec access • 2 wire analogue • 4 wire analogue 	<p>Equipment categories covered under 47 CFR, Part 68, including:</p> <ul style="list-style-type: none"> • ISDN Basic Access • ISDN Primary Rate Access • Digital Service Access: <ul style="list-style-type: none"> • 2.4 kbps • 3.2 kbps (2.4 kbps with Secondary Channel) • 4.8 kbps • 6.4 kbps (4.8 kbps with SC) • 9.6 kbps • 12.8 kbps (9.6 kbps with SC) • 19.2 kbps • 25.0 kbps (19.2 kbps with SC) • 56.0 kbps • 64.0 kbps (uses 72 kbps channel) • 72.0 kbps (56.0 kbps with SC) • 1.544 Mbps • 2-wire analogue tie trunks/ops • 4-wire analogue tie trunks/ops • PSTN-Voice Band (Analog) Access • Private Line (Analog) Access
<p>Radio transmitters subject to an equipment authorisation requirement, including:</p> <ul style="list-style-type: none"> • Short range devices, including low power devices such as cordless telephones/microphones • Land mobile, including: <ul style="list-style-type: none"> • Private Mobile Radio (PMR/PAMR) • Mobile telecom • Paging systems • Terrestrial fixed • Satellite mobile • Satellite fixed • Broadcast • Radio determination 	<p>Radio transmitters subject to an equipment authorisation requirement, including:</p> <ul style="list-style-type: none"> • Commercial Mobile Radio (Part 20) • Domestic Public Fixed (Part 21) • Domestic Mobile (Part 22) • Personal Communication Service (Part 24) • Satellite Communications (Part 25) • Broadcast (Part 73) • Auxiliary Broadcast (Part 74) • Cable Television Radio (Part 78) • Maritime (Part 80) • GMDSS (Part 80W) • Private Land Mobile (Part 90) • Private-Fixed Microwave (Part 94) • Personal Radio Services (Part 95) • IVDS (Part 95F) • Amateur Radio (Part 97) • Radio Frequency Devices (Part 15) • Fixed Microwave Services (Part 101)

Electromagnetic Compatibility

RELEVANT REGULATION	
EC	USA
<p>Council Directive 89/336/EEC, as amended by Council Directive 92/31/EEC, and Directive 98/13/EC of the European Parliament and of the Council and interpretation thereof.</p>	<p>Communications Act of 1934, as amended by the Telecommunication Act of 1996, (Title 47 of the United States Code).</p> <p>The US regulatory and administrative provisions in respect of equipment subject to electromagnetic requirements including:</p> <p>47 CFR Part 15 47 CFR Part 18 And FCC interpretation thereof.</p>
AFFECTED PRODUCTS	
EC	USA
<ul style="list-style-type: none"> Any product falling under the scope of Council Directive 89/336/EEC. 	<ul style="list-style-type: none"> Any products falling under the scope of 47 CFR Part 15 and 18.

Electrical Safety

RELEVANT REGULATION	
EC	USA
<p>Council Directive 73/23/EEC of 19 February 1973 as amended by Directive 98/13/EC of the European Parliament and of the Council.</p>	<p>29 USC 651 et seq. US 29 CFR 1910.7</p> <p>Products that are certified or approved under the Federal Mine Safety and Health Act (30 USC 801 et seq.) or its regulations and used in areas under the authority of the Mine Safety and Health Administration, are not covered under this Annex.</p> <p>OSHA will consider regulatory and legislative changes needed to support the objectives of the MRA.</p>

AFFECTED PRODUCTS	
EC	USA
<p>The electrical safety requirements of products falling under the scope of Council Directive 73/23/EEC on the harmonisation of the laws of the Member States relating to electrical equipment designed or use within certain voltage limits.</p>	<ul style="list-style-type: none"> The electrical safety requirements of products falling under the scope of 29 CFR 1910 subpart S. This includes the electrical safety aspects for workplace safety of medical equipment and telecommunication terminal equipment within the scope of those Sectoral Annexes. Products that are certified or approved under the Federal Mine Safety and Health Act (30 USC 801 et seq.) or its regulations and used in areas under the authority of the Mine Safety and Health Administration, are not covered under this Annex.

Recreational Craft

RELEVANT REGULATION	
EC	USA
<p>Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations, and administrative provisions of the Member States relating to recreational craft.</p>	<p>46 USC Chapter 43, 33 CFR 81, 84, 159, 179, 181, 183 and 46 CFR 58.</p>

AFFECTED PRODUCTS	
EC	USA
<p>Recreational craft as defined in Directive 94/25/EC.</p>	<p>Any product falling under the scope of 46 USC Chapter 43, 33 CFR 81, 84, 159, 179, 181, 183 and 46 CFR 58.</p>

Pharmaceutical Good Manufacturing Practices

RELEVANT REGULATION	
EC	USA
<ul style="list-style-type: none"> • Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, as extended, widened and amended. • Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, as extended, widened and amended. • Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products, as widened and amended. • Council Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use. • Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products. • Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products. • Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use. • Guide to Good Distribution Practice (94/C 63/03). • Current version of the Guide to Good Manufacturing Practice, Rules Governing Medicinal Products in the European Community, Volume IV. 	<ul style="list-style-type: none"> • Relevant sections of the United States Federal Food, Drug, and Cosmetic Act and the United States Public Health Service Act. • Relevant sections of Title 21, United States Code of Federal Regulations (CFR) Parts 1-99, Parts 200-299, Parts 500-599, and Parts 600-799. • Relevant sections of the FDA Investigations Operations Manual, the FDA Regulatory Procedures Manual, the FDA Compliance Policy Guidance Manual, the FDA Compliance Program Guidance Manual, and other FDA guidances.
AFFECTED PRODUCTS	
EC	USA
<ul style="list-style-type: none"> • Human medicinal products including prescription and non-prescription drugs; • Human biologicals including vaccines, and immunologicals; • Veterinary pharmaceuticals, including prescription and non-prescription drugs, with the exclusion of veterinary immunologicals; • Pre-mixes for the preparation of veterinary medicated feeds • Intermediate products and active pharmaceutical ingredients or starting materials • Human blood, human plasma, and human tissues and organs are excluded • Investigational medicinal products/new drugs, human radiopharmaceuticals and medicinal gases are excluded during the transitional phase, to be reconsidered at the end of the transitional phase 	<ul style="list-style-type: none"> • Human medicinal products including prescription and non-prescription drugs; • Human biologicals including vaccines, and immunologicals; • Veterinary pharmaceuticals, including prescription and non-prescription drugs, with the exclusion of veterinary immunologicals; • Type A medicated articles for the preparation of veterinary medicated feeds • Intermediate products and active pharmaceutical ingredients or bulk pharmaceuticals • Human blood, human plasma, and human tissues and organs are excluded • Investigational medicinal products/new drugs, human radiopharmaceuticals and medicinal gases are excluded during the transitional phase, to be reconsidered at the end of the transitional phase

Medical Devices

RELEVANT REGULATION	
EC	USA
<p>Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.</p> <ul style="list-style-type: none"> • Annex II (with the exception of section 4) • Annex IV • Annex V <p>Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.</p> <ul style="list-style-type: none"> • Annex II (with the exception of section 4) • Annex III • Annex IV • Annex V • Annex VI 	<ul style="list-style-type: none"> • The Federal Food, Drug and Cosmetic Act, 21. USC. §§ 321 et seq. • The Public Health Service Act, 42 USC. §§ 201 et seq.; • Regulations of the United States Food and Drug Administration found at 21 C.F.R., in particular, Parts 800 to 1299; • Medical Devices; Third-Party Review of Selected Premarket Notifications; Pilot Program, 61 Fed. Reg. 14,789-14,796 (April 3, 1996).

AFFECTED PRODUCTS	
EC	USA
<p>See: Sectoral Annex on Medical Devices, Appendix II</p> <ul style="list-style-type: none"> • Table I: Class I products requiring premarket evaluations in the US, included in a scope of product coverage at the beginning of a transition period, including: <ul style="list-style-type: none"> — Anaesthesiology, Dentistry, Ear/Nose/Throat, Gastroenterology—Urology, General Hospital, Neurology, Ophthalmology, Orthopaedics, Physical Medicine, Radiology, General and Plastic Surgery • Table II: Class II medical devices included in scope of product coverage at the beginning of the transition period, including: <ul style="list-style-type: none"> — Diagnostic ultrasound, diagnostic x-ray devices (except mammographic x-ray systems), ECG devices, ophthalmic instruments, blood pressure measurement devices, clinical thermometers, hypodermic needles (except anti-stick and self-destruct), external fixators (except devices with no external components), selected dental materials, and latex condoms • Table III: Medical devices for possible inclusion in scope of product coverage during operational period, including: <ul style="list-style-type: none"> — Anaesthesiology, Cardiology, Dentistry, Ear/Nose/Throat, Gastroenterology—Urology, General Hospital, Neurology, Obstetrics/ Gynaecology, Orthopaedics, Physical Medicine, Radiology, and General/Plastic Surgery 	<p>See: Sectoral Annex on Medical Devices, Appendix II</p> <ul style="list-style-type: none"> • Table I: Class I products requiring premarket evaluations in the US, included in a scope of product coverage at the beginning of a transition period, including: <ul style="list-style-type: none"> — Anaesthesiology, Dentistry, Ear/Nose/Throat, Gastroenterology—Urology, General Hospital, Neurology, Ophthalmology, Orthopaedics, Physical Medicine, Radiology, General and Plastic Surgery • Table II: Class II medical devices included in scope of product coverage at the beginning of the transition period, including: <ul style="list-style-type: none"> — Diagnostic ultrasound, diagnostic x-ray devices (except mammographic x-ray systems), ECG devices, ophthalmic instruments, blood pressure measurement devices, clinical thermometers, hypodermic needles (except anti-stick and self-destruct), external fixators (except devices with no external components), selected dental materials, and latex condoms • Table III: Medical devices for possible inclusion in scope of product coverage during operational period, including: <ul style="list-style-type: none"> — Anaesthesiology, Cardiology, Dentistry, Ear/Nose/Throat, Gastroenterology—Urology, General Hospital, Neurology, Obstetrics/ Gynaecology, Orthopaedics, Physical Medicine, Radiology, and General/Plastic Surgery

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ABOUT THE LEGATUM INSTITUTE SPECIAL TRADE COMMISSION

The Legatum Institute Special Trade Commission (STC) was created in the wake of the British vote to leave the European Union. At this critical historical juncture, the STC aims to present a roadmap for the many trade negotiations which the UK will need to undertake now. It seeks to re-focus the public discussion on Brexit to a positive conversation on opportunities, rather than challenges, while presenting empirical evidence of the dangers of not following an expansive trade negotiating path.

The STC draws upon the talent of experienced former trade negotiators from the US, Canada, Mexico, Australia, New Zealand, and Singapore, among other nations.

In the coming few months, the STC will host a number of public briefings that offer advice to key stakeholders on EU negotiations.

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All commissioners will serve the Commission in an individual capacity.

MISSION STATEMENT

The purpose of the Legatum Institute Special Trade Commission (STC) is to understand and guide the process that the UK and other governments are engaged in as a result of the Brexit referendum.

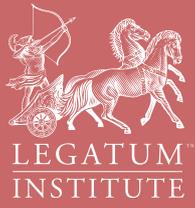
The Commission will provide the academic firepower to enable a successful process that includes:

1. The UK's relationship with Europe;
2. The relationship with the countries that more holistically embrace open trade, competition on the merits as an organising economic principle, and property rights protection;
3. The bilaterals with other key trading partners;
4. The relationship with the Commonwealth and developing countries; and
5. The underpinning WTO relationship.

The STC's combined expertise and experience, spread over two hundred years and hundreds of trade agreements puts it in a unique position to be a trusted and independent advisor to the series of post-Brexit processes that could and should lead to the creation of a global economic engine.

This realises the Legatum Institute's theory of change which is ultimately driven by the need to lift the global poor out of poverty and to create jobs, hope and opportunity for the world's people through the application of property rights protection and open trade systems that are characterised by competition on the merits as the organising economic principle.

The STC's role is to help shepherd governments, stakeholders and others towards increased global prosperity which is available if the inflection point in history that the Brexit vote represents is capitalised on.



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