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“New generation” trade agreements and their implications for social rights, public health and sustainable development

Report¹

Committee on Social Affairs, Health and Sustainable Development

Rapporteur: Mr Geraint DAVIES, United Kingdom, Socialist Group

Summary

The world's major trading nations seek to embrace new types of regional and bilateral trade agreements. With regard to Europe, these notably include CETA between the European Union and Canada, and TTIP between the European Union and the United States. These two trade agreements have not been negotiated transparently, nor have they received proper public and parliamentary scrutiny.

The agreements might enhance existing trade relations between the European Union, Canada and the United States, with economic benefits on both sides of the Atlantic. However, the overall gains may be relatively small and will not be evenly distributed. The report urges the negotiators to ensure that potential impacts are properly assessed and that the agreements do not empower corporate trade interests to trump public policies protecting the environment, food safety, public health and social rights.

The report thus addresses a series of recommendations to the European Union negotiators, relating to the Investment Court System provisions, climate policy objectives, international tax evasion and tax avoidance, and standards on health, food safety, environmental protection and social rights, as well as full reciprocity as regards public procurement provisions. Finally, the report calls for greater scrutiny of the ongoing negotiations by parliamentarians at both European and national levels.

1. Reference to committee: [Doc. 14085](#), Reference 4223 of 24 June 2016.



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A. Draft resolution²

1. The World Trade Organization has not concluded the latest Doha round of negotiations and the world's major trading nations have embarked upon negotiations for new types of regional and bilateral trade agreements. With regard to Europe, these notably include the Comprehensive Economic Trade Agreement (CETA) between the European Union and Canada and the Transatlantic Trade and Investment Partnership (TTIP) between the European Union and the United States of America. The Provisional Agreement of CETA has been signed by the two parties and its provisions that are within European Union competence already apply in the European Union. However, if the forthcoming Singapore–European Union trade deal case is so decided in areas of shared competence, it may require subsequent parliamentary consent by European Union member States.

2. CETA forms a template for TTIP, which is still being negotiated. The progress of TTIP may hinge on whether President-elect Donald Trump no longer wishes the United States to pursue it. The essential feature of these agreements is not the removal of the already small tariff barriers which would bring economic gains. Instead, the agreements propose regulatory co-operation, harmonisation of standards and, most controversially, new powers for transnational companies to use arbitration courts through an Investment Court System (ICS, the successor of the Investor State Dispute Settlement, ISDS) to sue member States for laws they pass that could impede future profits.

3. These two trade agreements have not been negotiated transparently and have not received public and parliamentary scrutiny. Occasional leaks on the substance of the talks have raised multiple concerns, especially in Europe. The agreements have the potential to enhance existing trade relations between the European Union, Canada and the United States, and economic benefits on both sides of the Atlantic may include increased annual gross domestic product growth, the creation of new jobs and the availability of a wider range of goods and services at lower prices. However, the overall gains may be relatively small and the economic impacts will not be evenly distributed, creating winners and losers. Therefore, the potentially unequal spread of the potential aggregate benefits within European society needs to be assessed.

4. Moreover, the negotiators need to also ensure that other fundamental costs and conflicts do not arise from these agreements. In particular, the agreements should not empower corporate trade interests to trump public policies protecting the environment, food safety, public health and social rights.

5. The proposed ICS introduces a new judicial system that allows investors to sue governments in private arbitration courts for profits they might not make due to laws passed to protect the citizen – including protecting the environment, public health and rights at work. These new investor powers are unnecessary as investors are already protected by established public and contract law in the European Union, Canada and the United States. If it is not removed from CETA and TTIP, the ICS will give powers in the Investment Chapter of these agreements to trump other public interest considerations, including the protection of the environment and public health. The ICS provisions should therefore be removed from CETA and TTIP.

6. In addition, there are widespread concerns over the impact of regulatory co-operation of these “new generation” trade agreements. Therefore, the Assembly believes that there is a need to carry out independent studies on the potential impacts of the ICS and the regulatory co-operation foreseen in CETA and TTIP. These should include potential impacts on water/air pollution, greenhouse gas emissions, food safety, consumer and workers’ protection and the sustainability of the public health system, as well as on the deregulation and liberalisation of public services in the framework of changes to public procurement provisions.

7. The agreements should not include powers for investors to trump environmental, democratic and human rights imperatives. The Parliamentary Assembly thus calls on the European Union negotiators to remain firm in their determination to protect and promote the interests of European citizens and to pay very close attention to the precise wording of provisions regarding the environment, food safety, public health, human rights and consumer protection, in order to:

7.1. ensure that the provisions of “new generation” trade agreements are fully compatible with and supportive of climate policy objectives, namely with the 2015 Paris Climate Change Agreement and do not include powers for investors to trump environmental imperatives;

7.2. make sure that these agreements support a fair and ethical trade system, and ultimately embrace strategies to combat international tax evasion and tax avoidance, including the use of shell companies in offshore jurisdictions by multinational companies;

2. Draft resolution adopted unanimously by the committee on 30 November 2016.

7.3. ensure that all parties are able to maintain their highest standards of health, food safety, environmental protection and social rights. The mutual recognition of standards, used for harmonisation purposes, should be applied only in cases where the safety equivalence test is fully satisfying. Failing this, existing high European standards must be upheld via, *inter alia*:

7.3.1. a stronger focus on applying the precautionary principle in setting regulations, to be explicitly included in the text of any agreement in order to limit the social, health and environmental risks and maximise the public benefits of these agreements;

7.3.2. maintaining clinical trials regulations which oblige companies to publish all clinical test reports for medicines allowed on the European Union market, as well as guaranteeing adequate whistle-blower protection;

7.3.3. strong safeguards in the labour rights chapter, explicitly stating the obligation of parties to abide by and effectively enforce the standards set in the International Labour Organization's core conventions;

7.4. guarantee full reciprocity as regards the opening of public procurement to external competition, including at sub-national level in the case of federal States;

7.5. establish a system to enable new protected geographical indications for particular countries and regions.

8. The "new generation" trade agreements should be designed to promote environmental sustainability, human rights and the rule of democratic law as well as to facilitate the mutual benefits of trade. In order to regain the public's trust in "new generation" trade agreements, as blueprints for future world trade, the Assembly calls on member States to open, as far as possible, negotiations to the scrutiny of democratically elected representatives at both European and national levels and to ensure that such agreements are subject to ratification by national parliaments insofar as they deal with shared competences.

B. Explanatory memorandum by Mr Geraint Davies, rapporteur

1. Introduction

1. On 13 June 2016, together with other members of the Parliamentary Assembly, I tabled a motion for a resolution entitled “Transatlantic Trade and Investment Partnership (TTIP) and its implications for social rights, public health and sustainable development” (Doc. 14085). In this motion we asked the Assembly to assess the risk that European social, health and environmental standards may be lowered as a result of the conclusion of the TTIP agreement. On 24 June 2016, the motion was referred to the Committee on Social Affairs, Health and Sustainable Development for report and I was appointed rapporteur.

2. The TTIP trade agreement between the United States of America and the European Union aims to increase market liberalisation and to remove economic trade barriers.³ It would create one of the strongest economic and investment alliances, and has the ambition to set global rules in the international trade arena by creating a free trade zone, promoting and facilitating investments and by adjusting national and European legislation. A similar agreement has also been negotiated and signed between the European Union and Canada: the Comprehensive Economic and Trade Agreement (CETA) contains a number of provisions that form the template for TTIP, including the investment protection and sustainable development chapters. The issues raised below apply equally to both CETA and TTIP.

3. TTIP goes beyond the scope of traditional trade agreements as it contains an important element of “regulatory co-operation”. It aims at maximising regulatory co-operation between the two largest internal markets in the world by making their regulatory systems more compatible, and at opening up a single public procurement and investment space.⁴ The agreement will encroach on many areas of public policy, in particular on environmental protection, public health and social rights.

4. The TTIP negotiations were launched in 2013, after the European Union ministers of trade gave a mandate to the European Commission to negotiate with the United States on behalf of the European Union. This agreement is still in the negotiation phase; initially, it was expected to be concluded by the end of 2016. According to the latest developments, the parties have not managed to find a consensus on any of the 27 articles of the agreement. Following the change in the United States leadership, TTIP may no longer be among the priorities of the new American administration. A forced pause in the intense negotiation process gives us an opportunity to take a closer look at the problems of the agreement – whether in TTIP, CETA or any other “new generation” trade agreement⁵ – and to consider whether there are opportunities to use it to promote not inhibit sustainable development, public health and the democratic rule of law.

5. In particular CETA and TTIP introduce new powers for transnational companies to sue European Union member States through arbitration courts meeting in private beyond the reach of public law. Governments become liable to compensate investors for laws they pass to protect their citizens' environment, public health and rights at work for impacts on future profit streams. Such powers thus punish or intimidate democracies regarding the passing of such laws.

2. Economic overview

“Not everything that counts can be counted, and not everything that can be counted counts.” Albert Einstein

6. According to the forecasts of the European Commission, TTIP would significantly boost trade between the two partners, which would create more business opportunities, enhance economic growth and ultimately, would generate more jobs. Lower prices and a wider variety of available products would also contribute to the prosperity of over 800 million European Union and American citizens. A study carried out for the European Commission suggests that TTIP could bring benefits to the EU economy worth an additional 0.5% of its gross domestic product (GDP).⁶ That is worth about a cup of coffee per person per week, but it will not be equally distributed. It is estimated that the sectors which will benefit the most from the agreement are metal products, processed food, chemicals, transport equipment, motor vehicles, etc.⁷

3. European Commission, The Transatlantic Trade and Investment Partnership (TTIP), TTIP explained, <http://trade.ec.europa.eu/>.

4. European University Association (EUA), Statement on TTIP and TiSA, 30 January 2015.

5. The committee subsequently changed the title of the report to reflect this.

6. The European Commission website, <http://ec.europa.eu/trade/policy/in-focus/ttip/about-ttip/questions-and-answers/>.

7. This study was carried out by the Centre for Economic Policy Research, using a model of the world economy, with a number of limitations. It is important to understand that the study makes certain assumptions about the agreement. The 0.5% growth calculations were based on the most ambitious scenario, which implied tariff barriers being reduced to zero, non-tariff barriers being reduced by 25%, and public procurement barriers being reduced by 50%.

8. The overall effect for the European economy would consist in increasing its productivity: as a result of the increased competition, companies would have to become more efficient. This, however, could have disastrous consequences for small companies, which would not be able to keep up with the pace of the competition.

9. As a matter of fact, the Commission's analysis does not take into consideration the distribution of economic gains. There is no analysis to support the assumption that the gains from TTIP would be spread evenly. It is far more likely that economic gains would be concentrated within a small section of society, with the majority of Europeans seeing little or no benefit.⁸

10. From an employment point of view, the study cannot quantify the number of jobs which would be created, since the modelled free trade agreements do not deliver employment effects. The European Commission made its own approximate calculation, and expects that the number of jobs dependent on exports in the European Union may increase by several million. This estimate is based on the general assumption that the increase in production demands more labour in a specific sector, having a positive effect on wages.⁹

11. In order to take rational decisions, the negotiators should also take into account the potential loss of thousands of small businesses: some studies estimate that TTIP may result in the loss of at least 680 000 jobs across Europe, caused by the inability of medium and small businesses to compete with US corporations.¹⁰ It would be equally important to take into account the costs of assisting workers in making the transition to new sectors through lifelong learning and other labour market flexibility programmes.

12. It remains of paramount importance to assess and scrutinise the assumptions more critically and from different viewpoints. For instance, the estimate that society at large will benefit from a wider variety of products (including processed food) at lower prices could be less attractive in view of certain facts. According to the studies conducted following the conclusion of the North American Free Trade Agreement (NAFTA), the intensification of the import of processed foods led to an increase in obesity, diabetes and an overall decline in public health in Mexico.¹¹ The negotiators should consider the costs of imposing countermeasures such as health labelling, advertising restrictions, or taxes on unhealthy foods.

13. In addition, the cost of imposing countermeasures such as health labelling, advertising restrictions or taxes on unhealthy foods could be multiplied many times by investors suing governments for introducing such protections and thereby restricting their profits. CETA and TTIP introduce new powers for transnational companies to sue governments in privately held arbitration courts through the Investment Court System (ICS), formerly the Investor State Dispute Settlement (ISDS). Therefore companies, for example, will introduce products that promote diabetes then sue governments for protecting the public from the poor health the companies are creating. That is why the ICS should be removed from CETA and TTIP as investors are already protected by public and contract law and there is no justification for these powers in these circumstances.

14. Moreover, some other unexpected costs may arise depending on the exact terms of some sectoral issues. For instance, while the environmental impact has been adequately assessed as far CO₂ emissions are concerned, a number of environmental aspects other than climate change were not included in the assessment model.¹²

7. Transatlantic Trade and Investment Partnership, The Economic Analysis Explained, http://trade.ec.europa.eu/doclib/docs/2013/september/tradoc_151787.pdf.

8. Ferdi De Ville and Gabriel Siles-Brugge, "TTIP: The Truth about the Transatlantic Trade and Investment Partnership", www.polity.co.uk/book.asp?ref=9781509501014.

9. Jacques Pelkmans and Arjan Lejour, "The Impact of TTIP: the underlying economic model and comparisons", October 2014, <https://www.ceps.eu/system/files/>.

10. Mark Dearn and John Hilary, "Rough trade. The threat of TTIP to small businesses in the UK", January 2016.

11. Sarah E. Clark and Corinna Hawkes, "Exporting Obesity, How U.S. farm and trade policy is transforming the Mexican food environment", 5 April 2012.

12. Jacques Pelkmans and Arjan Lejour, "The Impact of TTIP: the underlying economic model and comparisons", October 2014, <https://www.ceps.eu/system/files/>.

15. It is important to keep in mind that TTIP is a “new generation” trade agreement, involving regulatory co-operation, with only some elements of classical trade agreements. Given its unprecedented nature, its impact will be known only after the agreement takes effect. From the standpoint of all available evidence, so far only one fact is certain – European corporations as a whole will benefit from the transatlantic trade deal. In order to determine the limits of flexibility in the negotiation process, the negotiators should conduct a more complex assessment of potential economic benefits and costs involved. The Assembly should recommend a more careful and wider analysis, employing a broader range of determining factors, of the real economic potential of TTIP and other “new generation” trade agreements like it.

3. Main concerns and objections to the conclusion of TTIP

16. One of the issues related to TTIP which has raised the most concern is that the negotiations are being held behind closed doors, with even parliamentarians – the representatives of the people – only being given restricted access (if any) to the relevant documents. Many commentators consider this a democratic deficit that violates the fundamental principles of good governance, transparency and the right to information. While, to be fair, most international negotiations are carried out behind closed doors, the perceived lack of transparency combined with the wide scope of the envisaged agreement has fostered a growing mistrust among civil society and the general public, giving rise to suspicions that TTIP would undermine European consumer protection and environmental standards. These fears turned out to be justified in May 2016, with the release of secret TTIP negotiation documents by the non-governmental organisation (NGO) Greenpeace (Netherlands). The leaked information gave an unparalleled look at the scope of American demands to lower or circumvent EU protections for consumers, environment and public health.

17. TTIP aims at the harmonisation of the regulations of the two partners. It should be noted that the legislation of the European Union and the United States differs considerably, notably in the fields of nutrition standards, food safety and consumer protection. In 2000, the European Commission adopted the “precautionary principle” (Article 191 of the Treaty on the Functioning of the European Union), which requires a manufacturer to prove that a product is safe before putting it on the market, and intends to safeguard the highest environmental and health protection standards.¹³ The preventive policy-making process demands that politicians base a risk assessment on more factors than the existing scientific data in cases where there is scientific uncertainty. In contrast, the US approach puts the responsibility on the authorities to prove that a particular product is hazardous, before imposing a ban or refusing market authorisation. Where no such scientific data exists, the United States authorises companies to freely sell their products.¹⁴ Moreover, the TTIP papers, as disclosed last May, contain no mention of the “precautionary principle”.

3.1. Investment Court System

18. The primary concern about TTIP is that corporations would be granted a privileged voice to defend their interests through the Investment Court System (ICS), formerly the Investor-State Dispute System (ISDS) arbitration mechanism. It is foreseen in TTIP that investment provisions are to be separately enforced by ICS tribunals, which meet in private and have no obligation to publish their reasoning. This would entail a two-tier justice system, with international investors given access to ICS and domestic business (and citizens) subject to domestic law. ICS tribunals are not bound by the doctrine of precedent and are not obliged to cohere with other tribunals in their reasoning.

19. One principle objection to the ICS arbitration mechanism is that different classes of individuals are subject to entirely different sets of norms in terms of their relationship with the State and with the justice system, which is inimical to the rule of law. Lord Bingham, eminent British judge and jurist once said: “The law must apply equally to all, save to the extent that objective differences justify differentiation.”¹⁵ Investor-State arbitration courts were originally conceived in order to encourage foreign investments in States without independent courts. The ISDS first appeared in a bilateral trade agreement between Germany and Pakistan in 1959. The intention was to encourage foreign investment by protecting investors from discrimination or expropriation.¹⁶ Today the mechanisms are applied to States with independent judicial systems, free from

13. EUR-Lex, Access to European Union Law, <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=URISERV%3AI32042>.

14. See, for example, Assembly Recommendation 2017 (2013) “Nanotechnology: balancing benefits and risks to public health and the environment” for the case of an emerging technology where many risks, both to public health and to the environment, are as yet poorly understood, and regulations have struggled to keep up with the pace of scientific innovation.

15. Christopher May, *The Rule of Law: The Common Sense of Global Politics*, May 2014.

16. *The Economist*, Investor-state dispute settlement: The arbitration game, 11 October 2014.

political interference; thus, they no longer serve their original purpose. There is no compelling reason why foreign investors should have exclusive rights when their rights can be soundly protected in all European legal systems by established public and contract law and reinforced domestically by first instance, appeal and supreme courts. On the contrary, the case for democracy, human rights, the rule of law, the protection of public health and environment and public interest is stacked in favour of not including the ICS in CETA and TTIP.

20. Further consideration of the human rights legal aspects of the arbitration provisions, including legal uncertainty and transfer of power from accountable to unaccountable institutions, will be provided by the Committee on Legal Affairs and Human Rights, which is currently preparing a report on “Human rights compatibility of investor–State arbitration in international investment protection agreements”. In the present report, it is important to illustrate in practice how the ICS can be expected to undermine or penalise governments in their bid to protect the environment, public health and rights at work.

21. Companies will use the powers of arbitration courts made available to them. Germany is being sued for US\$3.7 billion by the *Vattenfall* energy corporation because of its decision to phase out nuclear power following the Fukushima disaster.¹⁷ Most recently, the US fracking company Lone Pine sued Canada for US \$250 million for a moratorium on fracking in Quebec, while US and European energy giants sued Argentina over a billion dollars for freezing energy and water prices. Trans-Canada has been taking legal action against the US government, suing it for \$15 billion as a result of its attempts to stop the mutual sand-oil pipeline project from being carried out, due to its impact on climate change and conflict with the Paris Agreement. In the case of *St Marys VCNA, LLC v. Canada*, a law which prohibited pesticides to protect the environment, was found to be in violation of Chapter 11 of NAFTA. One more violation of the treaty, involving regulations to control dangerous additives to petrol, was identified in the case of *Ethyl Corporation v. Canada*. The tobacco giant Philip Morris has filed to sue the Australian and Uruguay governments for anti-smoking packaging regulations to protect public health.

22. According to the European Commission, TTIP will guarantee governments' rights to regulate: ICS would not stop governments from passing laws in the interest of society. However, where new laws allegedly discriminate against foreign firms, it allows them to bring a claim for compensation.¹⁸ In this context, it should be understood that the ICS mechanism will inhibit and intimidate legislators from passing laws which protect the public interest, as the tribunals will be empowered to award damages in response to policies that allegedly affect the financial returns of foreign investors,¹⁹ even if these returns depend on damage to the environment, public health and rights at work, for example through promoting fracking, sugary drinks and diesel engines.

23. We may conclude that European efforts should be concentrated on continuing to use existing legal frameworks of public and contract law to protect both the investor and the public interest including legal harmonisation. They should not support the introduction of a new external system of law designed to favour investors' profit interests above public interest which trumps national law. Whilst it may be worth exploring alternative approaches to settle or even prevent investment disputes,²⁰ the existing legal framework already balances commercial and public interests through public law.

3.2. Regulatory co-operation

3.2.1. Environmental protection and sustainable development concerns

24. In the meantime, concerns have been raised about the significant implications of TTIP for environmental standards. Following the ratification of the Kyoto Protocol, the European Union has adopted the emissions trading system (ETS) with a view to eliminating greenhouse gas emissions in the sector of industries and aviation. The Fuel Quality Directive (FQD) has a similar objective in the sector of vehicles and transport.²¹ Such legislation creates a solid base for environmental protection, which US laws do not provide. The different approaches between the United States and the European Union on emission standards raise the problem of harmonisation – the question remains open as to whether TTIP could assimilate the lacuna of the

17. Thomas McDonagh, “Allowing corporations to sue governments for changing their laws may be common, but it's not good”, April 2014, <https://www.opendemocracy.net/ourkingdom/>.

18. The European Commission, Trade, <http://ec.europa.eu/trade/policy/in-focus/ttip/about-ttip/questions-and-answers/>.

19. Lew and Mistellis, “Arbitration of Investment Proceedings”, in *Comparative International Commercial Arbitration*, (London; Kluwer Law International, 2003), pp. 761-804.

20. Investor–State Disputes: Prevention and Alternatives to Arbitration, UNCTAD Series on International Investment Policies for Development, United Nations, New York and Geneva, 2010.

21. Fuel quality, European Commission, http://ec.europa.eu/clima/policies/transport/fuel/index_en.htm.

US legislation.²² The recent ratification of the Paris Agreement by the United States could be seen as a strong signal showing their readiness to work in the same direction as the European Union with regard to the reduction of carbon emissions.

25. However, the outcomes of Paris have not been integrated into TTIP with enforceable climate change imperatives and sustainable development goals. In fact the Environment Chapter has no legal teeth whilst the Investment Chapter has. This means environmental considerations will be consistently trumped in CETA and TTIP by ICS investor-protection provisions enforced through arbitration courts established to protect investors interests and not the environment. To make matters worse, Donald Trump has said his incoming US administration intends to change course on climate policies altogether. Even though the Paris Agreement is meant to commit signatories for three years plus a one year break clause, Donald Trump may well choose to frustrate Paris by not contributing to the £100 billion for technology transfer to the developing world and renege on the deal altogether.

26. Concerning the ambitious goal of TTIP to secure energy efficiency, we should keep in mind that the European Union and the United States also have completely different policies in the energy domain. The European Union sets priorities to increase the share of renewable energy sources in the energy mix, whereas the United States insist on the production of crude oil and gas. Consequently, there is a pressing need to debate controversial issues such as hydraulic fracturing, and to remain vigilant about any energy-specific provisions in TTIP.²³ This is particularly relevant to climate change imperatives as the latest satellite data suggests fugitive methane emissions of 5%, which would make fracking worse than coal for global warming,²⁴ and so is inconsistent with the Paris Agreement.

27. To a great extent, the policy of the United States concerning the usage of chemicals jeopardises environmental safety, in particular water resources protection. Currently, European importers and producers are obliged to disclose information about the chemicals they use to the European Chemical Agency (ECHA), which limits their usage if they are not compatible with environmental standards.²⁵ However, the Toxic Substances Control Act in the United States does not provide for the same regulations. Available drafts of TTIP indicate that it would include provisions addressing environmental protection and sustainable development. However, as mentioned, there is no equality of arms between the environmental provisions and the investment protection provisions. The investment protection provisions in TTIP have the advantage of a specific mechanism for enforcement: ICS. The sustainable development provisions have no equivalent mechanism. Thus, investment protection provisions will, in practice, trump sustainable development provisions. The agreement provides for significant disincentives for governments to violate the investment protection provisions but no such disincentives to violate the sustainable development provisions. Indeed, the investment protection provisions would put pressure on governments to depart from their sustainable development commitments for fear of being subjected to legal action in arbitration courts for compensation.

3.2.2. TTIP and public health

28. Public health is defined as “the art and science of preventing disease, prolonging life and promoting health through the organised efforts of society”.²⁶ Member States must ensure that public health protection is not trumped by commercial interests.

29. The pharma chapter in TTIP has provisions to reduce the total costs of medicines by 4% for US exports and by 5% for EU exports, by aligning current and future regulations. In fact, the removal of tariffs on the trade of pharmaceuticals and medical devices between the United States and the European Union has already been guaranteed by the Pharmaceutical Tariff Elimination Agreement (1995). Nevertheless, multinational companies claim that non-tariff barriers (NTBs) are still high, due to the ongoing existence of different non-harmonised standards and regulations.

30. However, whilst NTBs may include the costs of duplication of procedures, along with the costs of delays due to approval requirements, they also improve public health and save lives. A systematic study at Harvard University found that whenever the length of market authorisation reviews of drugs is shortened by 10 months,

22. European Parliament, Legal implications of the EU-US trade and investment partnership (TTIP) for the Acquis Communautaire and the ENVI relevant sectors that could be addressed during negotiations, www.europarl.europa.eu/.

23. Center on Global Energy Policy, Considerations for the Treatment of Energy in TTIP, <http://energypolicy.columbia.edu>.

24. For more information on this issue, please see my report on the exploration and exploitation of non-conventional hydrocarbons in Europe, Doc. 14196.

25. European Chemical Agency website, <http://echa.europa.eu/web/>.

26. World Health Organization, www.who.int/rpc/meetings/wr2004/en/index8.html.

it results in an 18% increase in serious adverse reactions, an 11% increase in hospitalisations, and a 7.2% increase in deaths.²⁷ Meanwhile, the European Commission estimates that adverse reactions to drugs kill nearly 200 000 Europeans each year.²⁸ Commercial efficiency should not be put before saving lives.

31. Europe is proud of the progress it has made on stricter EU regulation for clinical trials. The adopted regulation obliges companies to publish clinical test reports for medicine allowed on the EU market, which strengthens the possibilities for public oversight of medication and leads to greater transparency in the medical sector. Insisting on the importance of trade secrets and commercial confidentiality protection, the correspondent TTIP provisions may restrict the disclosure of clinical trial data so that positive trials could be publicised and negative trials suppressed. In addition, provisions for Trade Secrets would restrict “whistle-blowers” from disclosing risks. It is of the utmost importance that TTIP does not set back the positive developments of clinical trials regulation.

32. One of the objectives of the TTIP negotiations is to maintain and promote robust Intellectual Property Rights (IPR) frameworks and effective levels of intellectual property protection in the European Union and the United States. Despite its positive implications for international business, setting such a goal might result in limiting the accessibility of vital medicines: the changes in the IPR can imply longer monopoly periods, higher prices on drugs, and the appearance of new medicines with limited therapeutic value.²⁹ Meanwhile, the production of reasonably priced generics³⁰ would be hampered, and patients would experience difficulties in receiving affordable treatment. These provisions may be symptomatic of the negotiations being subjected to industrial lobbying behind closed doors.

33. TTIP deals with the questions of food safety and animal and plant health in a separate sanitary and phytosanitary (SPS) chapter. Many international organisations are working on the issue of food safety. For instance the United Nations issues the “codex alimentarius” in order to contribute to safety, quality and fairness in the international food trade. TTIP may change the rules due to an inconsistency between the definitions of the codex alimentarius and those set out in the trade agreement, where the definitions set by the World Trade Organization (WTO) would prevail. Particular concerns are caused by the possible liberalisation of the use of hormones or growth promoters for animals, as well as of genetically modified organisms (GMO) – which, for the moment, are restricted in Europe.

34. Cosmetic products include a wide range of commodities, such as toothpaste, sun protection products and creams for children. TTIP aims at the harmonisation of the safety tests, scientific safety assessments and product labelling, while speeding up the time taken to test and approve new products. However, harmonisation and speed should not be at the cost of lowering standards to common levels and hampering test innovation which improves safety at the cost of time. One of the main points to be approached during the negotiations would be the composition of the list of permitted and banned substances in cosmetics, which differs significantly between the United States and the European Union.³¹ A precautionary principle approach could be adopted to put public safety first.

3.2.3. Labour rights

35. With regard to the labour rights provisions in draft TTIP documents, we may argue that the United States and the European Union use somewhat outdated templates, which do not fully address the problems workers confront in fast-changing economies.³² The negotiators must be encouraged to replace previous

27. Donald Light, *New Prescription Drugs: A Major Health Risk With Few Offsetting Advantages*, 27 June 2014, Harvard University, <http://ethics.harvard.edu/>.

28. “Open letter to UK Prime Minister David Cameron and Health Secretary Andrew Lansley on safety of medicines”, *The Lancet*, Volume 377, Issue 9781, 4 June 2011, p. 1915.

29. See also Assembly [Resolution 2071 \(2015\)](#) “Public health and the interests of the pharmaceutical industry: how to guarantee the primacy of public health interests?”.

30. Medicines which are identical to “brand name” drugs in safety, quality, and performance characteristics.

31. For example, in the European Union, the REACH Regulation ([EC 1907/2006](#)) aims to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances. This is done by the four processes of REACH, namely the registration, evaluation, authorisation and restriction of chemicals, on the basis of the principle “no data no market”. The REACH Regulation places responsibility on industry to manage the risks from chemicals and to provide safety information on the substances. See http://ec.europa.eu/environment/chemicals/reach/reach_en.htm.

32. Susan Aaronson, *A Fresh Approach to Labor Rights and Employment in Transatlantic Trade and Investment Partnership*, CATO Institute, October 2015, <https://www.cato.org/publications/cato-online-forum/fresh-approach-labor-rights-employment-transatlantic-trade-investment>.

trade models with ones built on transparency, democracy and strong labour standards. Their leadership role should consist in drafting a trade agreement that places equal importance on fundamental social rights safeguards and on reducing tariffs and technical barriers to trade.

36. The main concerns are related to the fact that unlike the European Union, the United States has failed to ratify most of the core International Labour Organization (ILO) conventions.³³ Currently, under the US trade model, labour chapters are limited to the principles referenced in the ILO's 1998 Declaration of Fundamental Principles and Rights at Work. This allows the United States to preserve its statutory and regulatory inconsistencies with ILO conventions. We may conclude that limiting TTIP to the Declaration could give the United States a discriminating advantage with respect to labour markets (under the condition that European countries do not lower their labour standards in order to harmonise them with those of the United States),³⁴ which would be anti-competitive.

37. A labour chapter within TTIP and CETA should incorporate labour standards as defined by ILO conventions and jurisprudence, which would harmonise efforts towards meeting high and uniform international standards. Such an approach would prevent watering down the labour standards, while also eliminating ambiguities and facilitating understanding of the chapter by future signatories. Negotiators should also condition each country's participation on its adoption, implementation and effective enforcement of fundamental human rights reflected by the ILO conventions and jurisprudence.³⁵

38. The ILO should also be involved in the implementation of labour commitments through its co-operative activities, which tend to focus on technical assistance and the institutional capacity of trade partners. The comments of the ILO's supervisory mechanisms can be used to identify the critical areas that technical co-operation can address.³⁶

3.3. Deregulation of public services and public procurement

39. A brief analysis of the treaty text drafts known so far shows that Europe's public services might be under serious threat from TTIP. Public services ranging from health and education to social welfare and beyond have always been national affairs, requiring proper State regulation. Since making a profit is not their primary aim, they are often able to offer more affordable prices. Under TTIP, not only would many public services be open to commercialisation and liberalisation, but they would also face increased international competition, while privatisations and deregulation would become more difficult to reverse.

40. In essence, governments would be encouraged to externalise public services to private companies, which would be difficult to reverse without financial penalties. For example, the Dutch insurance company Achmea sued the Slovak Republic for reversing the health privatisation policies of the previous administration and was awarded €22 million in compensation under the investor rights provisions of a bilateral investment treaty. The threat of litigation may compel policy makers to avoid enacting new legislation and regulations that, while in the public interest, may have an impact on foreign investors. The proposed stabilisation clause in TTIP would lock in its deregulatory norms even after a State denounces the treaty. The proposed stabilisation clause will provide for the investment protection provisions to remain in effect (for any investment made while the treaty had effect) for up to 20 years after a State denounces the treaty. This means that TTIP and CETA will bind States even after they leave them and will fundamentally compromise their sovereignty.

41. The TTIP talks provide an opportunity to remove the remaining obstacles in the public procurement sector enabling EU firms to bid for a larger share of the products and services which US public authorities buy and to compete with US firms on the same grounds. At present, Europeans estimate that the openness of the EU procurement markets is at 85%, against 32% for the United States.³⁷ The EU procurement is more transparent due to the comprehensive coverage of all levels of procurement by uniform EU rules. In contrast, State and city government procurement in the United States is not fully covered by the WTO's Government Procurement Agreement (GPA) and procurement procedures vary from State to State. The major challenge in

33. https://www.ilo.org/dyn/normlex/en/f?p=1000:11200:0::NO:11200:P11200_COUNTRY_ID:102871.

34. Herrstadt O. (2015), TTIP: Time for a new approach to labor rights and standards. *Revista Derecho Social y Empresa*, 4, 113-127, www.digitalcommons.ilr.cornell.edu.

35. Owen E. Herrstadt, Labor Rights, Manufacturing, and the Transatlantic Trade and Investment Partnership, 3 September, 2013, www.epi.org/.

36. Executive Summary, Studies on growth with equity, Assessment of labour provisions in trade and investment arrangements, www.ilo.org.

37. European Commission, http://europa.eu/rapid/press-release_MEMO-12-201_en.htm?locale=en.

the field of public procurement in TTIP would be obtaining the US sub-federal government's agreement to be covered by rules that would make these markets more transparent for potential EU suppliers and free from provisions favouring local suppliers (such as, for instance, the Buy American Act).³⁸

4. Conclusions and recommendations

42. It is estimated that TTIP, being a trade agreement between the world's largest developed economies, would bring economic benefits to both partners amounting to 0.5% of GDP, although these benefits would not be evenly distributed. The challenge is to ensure that these small but significant benefits fully respect and support human rights, the rule of law and democracy, and that negotiations are transparent and publicly scrutinised so that public interest is prioritised over business interests. In addition, the agreement should provide a boost to both economies and also enhance and not undermine people's health and the environment on both sides of the Atlantic. If properly drafted, incorporating the needs of the environment, public health and human rights, it could help to provide a blueprint for world trade.

43. A solid, mutually beneficial trade agreement must provide for sustainable development, along with international rules for better trade that promote environmental, social and human well-being. Instead of granting privileged treatment for multinationals, it needs to guarantee their accountability and social responsibility through the enforceable protection of our public health, environment and human and social rights. It is of paramount importance that in the process of standard harmonisation, the respect of the highest standards is set as a priority.

44. Unfortunately, the evidence shows that, for the time being, TTIP and other "new generation" trade agreements, including CETA, have the potential to deregulate controversial and risky products, downgrade existing standards and influence policy makers in their decisions. The Parliamentary Assembly should therefore recommend that the European negotiators pay very close attention to the precise wording of provisions regarding the environment, food safety, public health, human rights and consumer protection set out in any such agreements, in order to ensure that all parties are able to maintain the highest standards that they deem necessary and appropriate. It is also of paramount importance that negotiations are opened to the scrutiny of democratically elected representatives, at both the European and national levels, and that they are subject to ratification by national parliaments insofar as they deal with shared competences.

38. European Commission, TTIP: Opportunities and Challenges in the area of Public procurement, Policy Department A: Economic and Scientific Policy.