EUROPEAN PARLIAMENT

At a Glance

Study in focus

ENVI RELEVANT LEGISLATIVE AREAS OF THE EU-US TRADE AND INVESTMENT PARTNERSHIP NEGOTIATIONS (TTIP)

BACKGROUND

In February 2013, the European Union (EU) and the United States of America (US) started the procedures necessary for initiating formal negotiations on a free trade agreement, referred to as the "Transatlantic Trade and Investment Partnership" (TTIP).[1] The first round of negotiations took place in Washington D.C. in July 2013, the seventh round ended on 3 October 2014 and the eight round is taking place in Brussels from 2 to 6 February 2015.[2] In order to monitor the on-going negotiations, the Committee on Environment, Public Health and Food Safety (ENVI) commissioned a study on "ENVI Relevant Legislative Areas of the EU-US Trade and Investment Partnership Negotiations (TTIP)". The study complemented a 2013 study on "Legal Implications of TTIP for the Acquis Communautaire in ENVI Relevant Sectors"[3] for the ENVI Committee. This leaflet presents the key findings of the 2014 study[4].

FOCUS OF THE STUDY

The stated objective of the TTIP negotiations (and subsequent agreement) is **to facilitate commercial exchanges of goods and services between the EU and the US and to enhance investments on each side**. This is to be achieved through **the removal of trade barriers including tariffs and non-tariff barriers such as differences in regulations**. This study analyses **the main differences** in EU and US legislation in eight TTIP-relevant areas, namely:

Medicines for human use and medical devices	**Cosmetics**	**Food and nutrition**	**Sanitary and phyto-sanitary**
Nanomaterials	**Cloning**	**Raw materials and energy**	**Motor vehicles**

KEY FINDINGS

1. Areas with significant differences

The analysis in this study suggests that in some cases, **the differences between EU and US legislation are so significant that they seem unlikely to be bridged**, in particular where the EU has a binding system in place whereas the US has a system which is partially binding or voluntary. This is the case in the area of **cosmetics** which is subject to mandatory notification and registration in the EU and where a strict safety assessment of substances contained in cosmetic products is required, whereas no registration is required in the US and safety testing is voluntary. This is also the case in the area of **cloning**, where the EU seems to be moving towards a ban on products from cloned animals, while the US considers such products to be as safe as those from conventionally-bred animals.

Directorate General for Internal Policies
Author: Dagmara Stoerring, Policy Department A on Economy and Scientific Policy
European Parliament
PE 536.301

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2. Areas with differences resulting from diverging approaches to risk analysis

In other areas, **the main differences are a result of diverging approaches to risk analysis** in the EU and US which may also be difficult to bridge. This is notably the case in the **food and nutrition sector** with regard to the approach taken to risk regulation of food safety. The EU applies the precautionary principle, which allows for regulatory action to be taken in the case of scientific uncertainty, whereas the US requires sound scientific evidence of harmful effects, before action is taken. This also applies in the case of **marketing approval of plant protection products** (PPPs). Contrary to the EU, in addition to the scientific risk assessment the US also considers the cost-effectiveness of PPPs, which may weigh in favour of approval of certain PPPs. As far as **medicines for human use** are concerned, in the EU, the Environmental Risk Assessment (ERA) is not taken into account in the risk/benefit analysis of the decision to grant (or deny) the Marketing Authorisation (MA). In the US, in cases where an Environmental Impact Statement (EIS) is required and therefore published at the time of approval, comments on the EIS may be submitted and may be taken into account by the Food and Drug Administration (FDA) to consider beginning an action to withdraw the approval. In the area of **medical devices** there is no specific requirement for an ERA in the EU, whereas devices in the US are subject to rules similar to those applicable to medicines for human use.

3. Areas with differences of a technical nature

In areas where **differences between EU and US regulatory systems are mainly of a technical nature** (e.g. technical environmental standards for **motor vehicles**), greater convergence could potentially be achieved through increased technical cooperation or through mutual recognition of environmental regulations in place (provided this does not lead to a lowering in the level of environmental protection on either side).

4. Areas with no binding regulations

Finally, in areas where **there are currently no binding regulations on either side of the Atlantic** convergence may be easier to achieve through scientific and technical cooperation and better coordination of EU and US regulators in certain areas. This is notably the case for **nanomaterials** for which there is currently no specific legislation in place in either the US or the EU (with the exception of some labelling requirements in the EU). In the area of **raw materials and energy** neither the US nor the EU have adopted a single economy-wide legislation for **the exploitation of shale gas** and harmonisation of regulatory standards through TTIP appears unlikely. **Fuel quality legislation**, and in particular the need for clear EU rules on calculating the GHG intensity of fossil fuels, has the potential in EU-US trade relations.

Scan QR code to access the study:

[1] See EU Council, Council approves launch of trade and investment negotiations with the United States, Press release, Luxembourg, 14 June 2013; available athttp://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/EN/foraff/137485.pdf

[2] See http://trade.ec.europa.eu/doclib/press/index.cfm?id=1154 and http://ec.europa.eu/trade/policy/in-focus/ttip/

[3] EP (2013), Ecologic Institute and BIO Intelligence Service, Legal Implications of TTIP for the *Acquis Communautaire* in ENVI Relevant Sectors, IP/A/ENVI/ST/2013-09,PE507.492; available at: http://www.europarl.europa.eu/RegData/etudes/etudes/join/2013/507492/IPOL-ENVI_ET(2013)507492_EN.pdf

[4] EP (2014), Ecologic Institute and BIO Intelligence Service, ENVI Relevant Legislative Areas of the EU-US Trade and Investment Partnership Negotiations (TTIP), IP/A/ENVI/2014-03, PE 536.293 available at: http://www.europarl.europa.eu/RegData/etudes/STUD/2014/536293/IPOL_STU(2014)536293_EN.pdf