European Commission

TTIP AND REGULATION:

AN OVERVIEW

The European Commission

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About this document

This paper provides an overview of the EU's positions in the negotiations on regulatory cooperation.

Making EU and US regulation more compatible is at the heart of the negotiations on a Transatlantic Trade and Investment Partnership (TTIP). It has the most potential to contribute towards jobs and growth of any part of the negotiations. It will also deliver greater consumer choice and stronger, not weaker, regulatory outcomes.

The impact on regulation has also driven much of the public discussion on TTIP. Some have expressed the fear that more compatibility between EU and US regulations may lead to lower standards for health and safety, the environment, consumer protection or financial stability. This is not the case.

This paper will outline the EU's TTIP objectives by answering three questions:

1. Why does regulatory cooperation matter in TTIP?

2. How will TTIP uphold protection in the EU and the US?

3. What are our actual proposals?

More detail on all of these topics can be found on the on the European Commission's TTIP website.

1. Why does regulatory cooperation matter in TTIP?

Governments regulate to protect people from risks, in particular, to their health and safety, the environment etc. But differences in regulation can also restrict trade. Some of these differences are unavoidable, especially when the objectives of regulations are different.

In many cases, however, regulations are different for reasons unrelated to the level of protection they aim at, for instance because regulators in different countries developed solutions on the basis of domestic considerations rather than in cooperation with regulators from other countries. In these cases, regulatory cooperation can avoid unnecessary divergences or inconsistencies and make it easier to trade products and supply services, lowering costs and boosting economic growth. These are the differences that TTIP intends to address.

The European and American systems of regulation are among the most advanced and sophisticated in the world. They effectively protect people, and in most instances to a similar extent, although often in different ways.

This also means that there is a great deal of potential for regulatory cooperation to create new economic opportunities and greater consumer choice. It should also lead to better quality, more thoroughly enforced regulation, and increase our ability to influence the quality of global rules.

Four Reasons Why Regulatory Cooperation Matters

1. Jobs and growth

Making regulations in the EU and the US more compatible will lower the costs of trading across the Atlantic. That will mean companies will be able to reach new customers and expand their businesses, creating growth, new jobs and higher wages.

This works because companies can avoid a series of unnecessary costs that arise from developing and manufacturing two different sets of products for sale in either side of the Atlantic, carrying out duplicative testing and certification of conformity, or complying with other diverging or inconsistent regulatory requirements. Cost like these can constitute prohibitive entry barriers for many companies, in particular for SMEs. They can be addressed without in any way affecting the level of protection afforded by the regulations from each side. The TTIP regulatory cooperation work is focusing on sectors that already employ over 30 million people in Europe – e.g. pharmaceuticals, engineering cars and medical devices (see 3.2 for full list). However, all sectors of the economy should benefit. Small and medium sized enterprises will be among the biggest beneficiaries, since they are disproportionately affected by regulatory barriers to trade.

2. More choice for consumers

Where EU and US regulations become more compatible, consumers will have more products to choose from.

For instance, car manufacturers believe that TTIP would make it possible for them to sell a

broader range of models in both Europe and the US. Reduced trading costs should also lead to lower prices.

3. Stronger regulation, better enforced

TTIP will not mean lower levels of protection or safety (see 2). On the contrary, where TTIP boosts regulatory cooperation, consumers are likely to have better guarantees that they buy safe and legal products.

Both sides have some of the highest quality regulation in the world, managed by some of the most qualified experts. Regulatory cooperation means sharing that pool of talent, experience, and scientific knowledge, to the benefit of both sides.

It will also mean stronger enforcement of rules, which is a key challenge for public authorities. Where TTIP removes unnecessary duplication (as in factory inspections for medicines and medical devices) it will free up resources for more worthwhile tasks.

Closer EU and US cooperation will also help address shared challenges like making sure products imported from other countries follow our rules. However, it will not allow products on the EU market that do not meet EU requirements.

4. Greater influence on the international stage

We live in a global economy so solving regulatory problems requires international cooperation. Many regulatory issues are discussed in international organisations.

Closer regulatory cooperation between the EU and the US under TTIP could give a push to the development, update and implementation of international regulation and standards. If the US and the EU agree on an approach the chance of it being adopted by others is much higher.

This kind of partnership will only become more important over time as emerging economies play a larger international role.

Increased EU-US cooperation will contribute to lowering trade barriers world-wide. Moreover it will help ensure that international rules provide the highest possible levels of protection and reflect the values of respect for the individual, the rule of law and open markets that Europe shares with the United States.

2. Why will TTIP not lower existing protection in the EU or the US?

The public debate on the TTIP agreement in many EU countries is a positive step for European democracy. The more opinions expressed, the better informed the outcome will be.

However, many concerns have been expressed. It is important to set the facts straight and dispel possible misunderstandings.

To be clear:

TTIP will not lower regulatory protection for people or the environment.

The examples listed throughout this note show that there are many areas where the EU and US regulations provide for a similarly high level of protection. In these cases we will be able to make our systems more compatible, without lowering protection.

In other areas the EU and the US have different approaches to regulation, implying different levels of protection.

For instance, the EU has very detailed legislation that lays out when and how **genetically modified products** can be grown or sold in the EU. Our rules do allow some products to be imported and grown but they are much stricter than comparable US rules.

In a case like this, it is not possible to make the systems compatible, because we have taken different democratic decisions through our legislative processes about what rules are right for our societies. TTIP will do nothing to change those laws.

The same goes for **hormone-treated meat**. EU legislation lays down requirements on this, and that will not change because of TTIP.

A similar but distinct example is the chemicals sector.

The EU and US regulate chemicals in different ways. The main European legislation – known as REACH – requires that chemicals sold in Europe be registered with the European Chemicals Agency. The registration must be accompanied by a comprehensive set of data. US law – contained principally in the Toxic Substances Control Act – does not require such registration or submission of data.

Here again, TTIP is not going to change the underlying legislation. There is no question of any substances being sold in the EU without complying with the REACH requirements, regardless of whether they can be marketed or used in the US.

TTIP will not affect the right of either side to make new regulations.

Nothing in the TTIP will undermine the EU treaties or Member State Constitutions which lay down the right of governments to make laws and regulations in the public interest.

The TTIP text will explicitly reaffirm the sovereign right to adopt new regulatory initiatives, to regulate in pursuit of legitimate public policy objectives and to ensure that our laws and policies provide for and encourage high levels of environmental, health, safety, consumer and worker protection and financial stability, as provided for in the EU Treaties.

The EU's goal for forward looking cooperation on future regulation is to encourage authorities to cooperate as early as possible in their regulatory activity.

The aim will be to avoid, whenever possible, technical differences that are unnecessary and which only increase compliance costs

without providing any benefit in terms of protection.

If they are not able to find solutions like these, however, regulators will be free to go their own way, as is already the case today. TTIP would in no way force them to put trade or economic considerations above the protection of public policy interests in their future decision-making. TTIP will also not introduce requirements in our decision-making process that could delay regulatory action.

TTIP will not circumvent parliaments, governments or stakeholders' roles in the regulatory process.

The agreement will not change the principles and the procedures set out in the EU treaties defining how our regulations should be made.

That means that the European Commission will continue to make proposals and the European Parliament and the Council of the European Union will continue to be co-legislators. More detailed rules will continue to be adopted through delegated and implementing acts, in accordance with the EU's Treaty. TTIP itself will need to be fully, democratically and transparently approved by both the European Parliament and EU Member States.

Once TTIP is adopted, regulatory cooperation will not change the way each side makes regulation. Both sides are expected to exercise transparency towards each other and to the public in making known their regulatory intentions. This will support more informative interaction among regulators and promote better regulatory outcomes.

Both sides have very high levels of regulatory protection.

EU regulations are of very high quality but it is a myth that they always offer a higher level of protection than those of the US. In a number of areas the US has some of the most developed and effective regulations and enforcement mechanisms in the world.

For instance, in America many cosmetic products such as sunscreens are considered to be over-the-counter medicines, meaning they must be scientifically assessed and approved by the authorities before they can be sold to consumers.

In Europe cosmetic companies must demonstrate their products are safe and use safe ingredients. Then they can register their products before putting them on the market.

This does not mean that the EU needs to copy the US regulations, or vice versa, or that the EU offers a lower level of protection. It is simply a difference of approach.

3. How will the TTIP text on regulatory cooperation be structured?

We can broadly divide the likely future provisions on regulation in two groups.

Horizontal parts of TTIP will look at how we regulate and outline shared principles and best practices. It will also identify ways for regulators to cooperate.

The **sectoral** parts will look at the rules governing specific economic sectors. They will try to reduce unnecessary duplication of regulatory requirements as well as setting an agenda for future cooperation.

Two other parts of the agreement – the work on customs and the work on SMEs - are also relevant to the work on regulatory cooperation.

TTIP Benefits

Electric cars

We are already doing this with electric cars, for example, where EU and US authorities are working on common standards for plugs and infrastructure that will be needed to make them work on a large scale.

3.1. Horizontal provisions

3.1.1. Regulatory cooperation

The first part of the regulatory pillar would cover systems to promote cooperation between regulators on both sides.

The goal is to put in place systems that would allow the EU and US regulators to interact with their counterparts as they develop new rules and review existing ones.

Neither side will adopt the other's approach to regulating. The aim is to build bridges between the two systems. By working together early on in the process, the EU and US authorities can share expertise and ideas on the best way to tackle issues requiring regulatory action. This should lead to regulation that is more compatible but which can also be more effective and efficient. That would mean fewer barriers to trade, better quality regulation and more effective enforcement.

Again, nothing would stop either side from going their own way if no agreement is possible, but both sides would commit to the principle of dialogue and to consider different options.

Issues discussed under this chapter include good regulatory practices, such as consultation of stakeholders; and ways that impact assessments can more precisely identify not only the social and environmental effect of proposed regulations, but also impacts on international trade.

3.1.2. Handling future regulatory challenges through a regulatory cooperation body

The EU is proposing that the TTIP creates a Regulatory Cooperation Body, composed of senior representatives of EU and US regulatory authorities, to set priorities for regulatory cooperation work.

A joint body would act as a forum to share ideas and plan cooperation on new technologies and risks and our regulatory responses to them.

The body would provide a forum for exchanges between regulators on these types of questions. It would not have the power to adopt legal acts. None of its activities can replace the respective administrative and regulatory procedures on either side of the Atlantic. Decisions on regulation will remain in the hands of domestic regulatory and legislative bodies or institutions.

The body will also be a way to set priorities and bring more transparency to existing regulatory cooperation work, which currently happens on an *ad hoc* basis.

The body will publish regular reports and interact with outside stakeholders like trade unions, consumers, business, NGOs and the general public. To be clear, none of those stakeholders – neither business nor anyone else – would be members. The body would also need to involve EU and US legislators.

3.1.3. Technical Barriers to Trade

Countries often establish technical requirements on the design of products, so that they are safe, compatible with other systems (e.g. mobile phones and networks) and of high quality.

When these requirements are different between two markets, like Europe's and America's, they can act as trade barriers by forcing businesses to make two different products, even though both may be equally safe.

The testing required to make sure products follow the technical requirement (known as conformity assessment) can also act as a barrier because it may be more difficult or costly for foreigners to have their products tested and certified than for home producers.

TTIP Benefits

Making product requirements and testing more compatible

The EU wants the TTIP to help create more common or compatible EU and US technical requirements and conformity assessment procedures – without lowering levels of protection.

That could be done for instance by encouraging EU and US standard-setting bodies to look at standards produced on the other side of the Atlantic when developing their own. It could also be done through cooperation between EU and US authorities.

Differences in standards and conformity assessment procedures have been identified as a major obstacle to EU firms exports to the US, particularly SMEs.

One of the most significant achievements of international regulatory cooperation is the World Trade Organisation's agreement on technical barriers to trade (TBT), an early version of which came into force in 1980.

The agreement covers laws, regulations and standards that concern the characteristics of products and how they should be labelled, as well as the methods to check if products meet these requirements.

When the product characteristics are laid down in a binding piece of law, this law is called a technical regulation. When the product characteristics are not legally mandatory, they are called standards.

Standards describe specific technical solutions, are consensually drafted by all stakeholders and can be used in support of technical regulations.

The procedures to check if a product complies with a technical regulation or standard are called conformity assessment procedures.

WTO rules require that all of the above be non-discriminatory and no more trade-restrictive than necessary to achieve their legitimate objectives, like health, safety, consumer or environmental protection.

In TTIP, the EU would like to go beyond existing rules in the WTO TBT agreement wherever possible. The objective is to maintain a high level of safety of traded products, while avoiding unnecessary trade barriers that add nothing to levels of protection, and spurring growth and jobs.

The EU's ideas include:

- Joint EU-US work in the international bodies that prepare technical regulations and standards
- Promoting closer cooperation between EU and US standard setting organisations.
- Promoting greater acceptance by the US of test results from laboratories in the EU for the purpose of US conformity assessment procedures
- Increasing transparency in the preparation and adoption of technical regulations and standards.

3.1.4. Sanitary & Phytosanitary Measures

Sanitary and phytosanitary (SPS) measures are laws and regulations that promote food safety and animal and plant health. They are essential to protect people's health and for maintaining public confidence in the farming and food sector, which provides incomes for many Europeans, in cities and in the countryside.

As already stated, the EU and US have different views on some areas of food regulation but in many others our approaches are closer. By strengthening cooperation in these areas TTIP can create new opportunities for many Europeans.

TTIP Benefits

Speeding up procedures for agricultural exports

The US has strong rules to stop new pests or diseases from accidentally entering their environment with imports. This means that European product need to be approved by US authorities before they can be sold there.

The problem is that this process takes years – 12 years and counting in the case of European peaches for example – to the detriment of EU producers.

The EU is proposing that TTIP include clear timelines and procedures for the approval and certification process and that in some cases EU rules and controls could be considered equivalent to US controls, eliminating the need for US inspections altogether.

Recognising when our food standards are really equivalent

The EU and US do have different attitudes to some aspects of food safety. But in other cases we just have different, but equivalent solutions to the same problem.

For instance, to make sure that oysters are free of dangerous bacteria, the US tests the water in which oysters are reared. In Europe we test the oyster itself. Scientists confirm that both ways are equally effective.

TTIP creates an opportunity for our authorities to come to agreement. If they can, Dutch and Spanish oyster producers would gain access to a new, lucrative market.

Like the TBT negotiations these talks are focused on building on WTO rules. The 1994 WTO agreement on sanitary and phytosanitary (SPS) measures aims to make sure that safe – and only safe – products can be easily traded and to prevent the spread of animal or plant diseases (like mad-cow disease or bird 'flu).

It lays down basic rules on issues like the use of international standards and following scientific principles.

As above, the EU sees TTIP as an opportunity to go beyond the WTO rules.

Our ideas include:

- Improving the speed, predictability and transparency of procedures for approval of imports from particular farms and food processing plants.

- Both sides applying their SPS rules to the entire territory of the other as a whole, given that the same food safety rules apply across both entire territories. The US does not always recognise that all EU Member States apply the same rules.

- Both sides accepting the principle of "regionalisation" when it comes to specific disease outbreaks. Diseases may have a very small geographical range. If they are well contained, there is no reason to block exports from the other sides entire territory.

- Recognition of equivalence of specific rules, testing procedures and inspections

3.2. Sectoral provisions

The EU believes that any serious agreement on regulatory cooperation should also look at specific regulation applying to particular economic sectors.

Since the beginning of the negotiation regulators from both sides have been working intensively to identify areas where TTIP can result in concrete regulatory savings in particular sectors.

The work should aim to remove existing barriers to trade without in any way undermining regulatory objectives. It should also set out an agenda for future cooperation as the agreement is implemented.

The EU has so far made proposals in seven sectors (chemicals, cosmetics, the engineering sectors, medical devices, motor vehicles, pharmaceuticals, and textiles). It should be noted that in several of these areas transatlantic industry is pursuing common regulatory goals. Below is a summary of the main EU proposals.

3.2.1. Chemicals

Current EU and US regulations on chemicals differ significantly so neither harmonisation nor mutual recognition is feasible.

The EU sees scope for working together in four areas, within the limits of our respective rules, to:

- prioritise chemicals for assessment
- align the classification and labelling of chemicals
- identify and address new or emerging issues
- make it easier to share data whilst protecting confidential business information.

Doing this could make our systems more efficient and thereby cut firms' and regulators' costs.

TTIP Benefits

Working together during chemicals assessments

Although they are very different, there are areas where the EU and US systems for regulating chemicals allow for joint work. For example, regulators could agree to work together during their assessments of the same chemicals.

The procedures for evaluating chemicals would not change but the regulators could assess the same substances at the same time and exchange information as they do so.

This would save costs for both the companies as the same tests could be used at the same time and the regulators, who have to evaluate the tests – but it would not change the level of protection offered by EU law.

3.2.2. Cosmetics

EU and US regulators already work closely on cosmetics. The EU proposes taking this further by, insofar as possible:

- Approaching our scientific assessment methods and the way products are tested
- developing and using alternatives to animal testing
- aligning each other's requirements for labelling
- working more closely together through the International Cooperation on Cosmetics Regulation (ICCR), which brings together regulators from the EU, the US, Canada, Japan and Brazil.

TTIP Benefits

Facilitating trade in sunscreen

In the EU, only scientifically assessed, safe and authorized UV filters can be used in sunscreens.

In the US also, but a different authorization procedure applies. Consequently, manufacturers have to apply for authorization in the EU and the US based on different safety assessments.

TTIP can foster the exchange of scientific assessments of existing and new UV filters between regulators from both sides and therefore speed up the authorization of products already approved for one market in the other one.

Consumers would therefore benefit from a wider range of innovative and safe products.

3.2.3. Engineering

Engineering industries include mechanical, electrical and electronic equipment and products.

TTIP Benefits

Making it easier for European mechanical engineering exporters to compete in the US.

Europe is very successful at making the machines used in factories to manufacture other products. Exports to the US are hindered because the US often doesn't apply international standards (ISO/IEC standards in this case) and because of the high costs of conformity assessment.

Because only few of these products are made at a time – they are tailor-made for each customer – fixed costs like these are high.

The EU believes that TTIP can be a way to get American and European machinery regulators working more closely together, in order to facilitate trade.

The EU is proposing that TTIP:

- provide a basis for cooperation between regulators with a view to promote the alignment of future regulations
- encourage cooperation between relevant standard-setting organisations with a view to elaborating in the future insofar as possible common standards;
- provide for cooperation on between enforcement authorities
- examine ways to streamline conformity assessment procedures and avoid duplicative testing or certification

3.2.4. Medical Devices

The EU believes TTIP may help deepen cooperation with the US on medical devices in a number of areas, including:

- quality management systems (QMS) audits. These are inspections of manufacturers to ensure they have systems in place to produce safe products. Recognition of each other's inspections would save time and costs for both regulators and industry.

- systems for identification and traceability of medical devices. Known as unique device identifiers (UDI), if these were harmonised they would be more effective and more efficient.

- submission forms for companies asking authorisation for marketing new products. A common submission would make it easier to apply for approval in both jurisdictions at the same time.

TTIP Benefits

Unique device identifiers for medical devices.

Being able to identify individual medical devices (e.g. pacemakers or artificial hips) is essential in the case of product recalls.

Both sides are now working on future identification systems for medical devices. If these are compatible, it will boost trade and also guarantee that products can be traced when needed, no matter where they were produced.

3.2.5. Motor Vehicles

The EU's aim is for TTIP to achieve more compatibility between motor vehicles regulations without lowering standards on either side.

TTIP Benefits:

Recognising car safety standards

The safety regulations that apply to cars are different in the US and the EU - even if the end result is comparable levels of safety. In fact, it is already possible to drive some US-approved cars on European roads, under a special European approval system.

Through TTIP, the Commission would like regulators to formally recognise that important parts of our two regulatory systems are broadly the same in safety terms and could be accepted on both sides of the Atlantic.

This would be a major boost to trade in the car sector, since regulatory differences are estimated to have a much higher impact than tariffs on the cost of exporting to the US.

The EU has three main objectives:

- recognising a critical mass of each other's existing standards and regulations
- for other existing regulations, developing a medium-term programme to develop global safety regulations through the United Nations Economic Commission for Europe (UNECE)
- working together more closely to draw up regulations in future, especially on new technologies.

3.2.6. Pharmaceuticals

Medicines regulators already work closely together.

The EU proposes several areas for further joint work, including:

- recognising each other's good manufacturing practice (GMP) inspections of manufacturing plants, to avoid duplicating work and costs;
- allowing the exchange of confidential information to support more joint assessments of new medicines
- harmonising our requirements for approving 'biosimilars' - products similar to already-licensed biological medicines.
- streamlining systems for authorising generic drugs
- working together to upgrade international guidelines on testing of medicines for children.

TTIP benefits

Getting rid of redundant inspections

Factories that make products like medicines and medical devices need to be inspected by the authorities to make sure that they produce safe, high quality products.

The same goes for establishments producing our food. Today if producers want to sell in both the EU and US markets they have to be inspected by authorities from both sides, sometimes even for compliance with the same rules. That is an unnecessary cost to the producers.

More importantly, redundant inspections are an inefficient use of our authorities' resources.

The EU wants TTIP to formalise trusting relationships between authorities on both sides, so that they can rely on each other's inspectors, saving time and money for everyone – while making sure people are even more safe by using authorities' limited resources more productively.

3.2.7. Services

Regulation does not only apply to manufactured goods. Service sectors are often some of the most heavily regulated parts of the economy, and with good reason.

We know for example that the finance sector needs to be very closely managed and that we need strong regulation to make sure our professional services providers are properly qualified. The extent of the regulation in services means more potential from regulatory cooperation.

TTIP Benefits

Creating new opportunities for European professionals to practice in the US and vice versa

The EU believes TTIP should also create opportunity for individuals. That is why we want professionals to be able work freely on both sides of the Atlantic.

The EU is proposing that TTIP establish ways for both sides to facilitate recognition for selected regulated professions.

Strengthening financial stability.

One of the lessons of the 2008 financial crisis is that risks to financial stability do not respect borders. This is why governments stepped up international coordination through bodies like the G20 and the International Financial Stability Board in the crisis' aftermath.

The EU believes that TTIP can also contribute to this coordination by making sure that the world's two largest financial services markets – which make up the core of the global system – implement general international rules in more compatible ways.

Both sides would be free to make prudential regulation for financial stability, but that regulation would be more effective since it would be more consistent and thus increasing the financial stability.

For example, we are implementing now rules related to the derivatives trade, which was at the heart of the financial crisis. Our cooperation there has been useful, but could have been more effective and efficient if we had a structured relationship.

The EU believes that there is significant potential for future cooperation on services, in areas like:

- Financial services
- Recognition of professional qualifications
- Telecommunication services
- More transparency in the way services regulation is made

3.2.8. Textiles and clothing

The EU is proposing to strengthen existing transatlantic cooperation in three main areas:

- Labelling, including mutual recognition of care instruction symbols and the alignment of the names of new textile fibres.
- product safety and consumer protection – including working jointly towards clarifying requirements on fire safety of fabrics – and
- voluntary standards and testing methods - seeking convergence in areas like protective clothing, technical textiles and child safety.

TTIP Benefits

Safe products and easier trade in textiles

Clothing is not often thought of as a dangerous product but whether because of flammability or faulty protective clothing it can pose real risks to consumers. It is also one of the world's most global businesses. Both the EU and US import and export vast quantities of clothing.

Encouraging cooperation on assessing the safety of clothing would make enforcement of the rules easier on both sides.

3.2.9. Regulatory Cooperation and SMEs

Smaller businesses are disproportionately affected by regulatory barriers to trade. Complying with regulation is often a fixed cost, that is the same no matter the size of the company, meaning that this cost is proportionately more significant for smaller firms. The work on regulatory cooperation across the board is therefore likely to seriously benefit SMEs.

TTIP Benefits

Helping small and medium sized enterprises (SMEs) find out what regulations they have to comply with.

Smaller companies have limited resources to keep up with regulation on foreign markets. The effort of just finding out can be enough to keep them out of a new market.

The EU therefore wants each side to establish a website that gives SMEs easy access to all the rules that apply to their products in each market, as well as all the commitments made under TTIP. The site should include an online search tool so that this comprehensive information can be obtained in one go simply by typing in a standard international code for their product.

The EU wants to make sure that SMEs are able to take advantage of these benefits by including a dedicated SME chapter in TTIP.

It would include:

- a commitment by each side to establish a website that gives SMEs easy access to all the rules that apply to their products in each market, as well as all the commitments made under TTIP. (see example 1 in section 1)

- strengthened EU-US cooperation and exchange of best practices on pro-SME policies.

- a dedicated SME committee to monitor TTIP implementation from an SME perspective and make sure that their special needs are taken into account.