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POLICY DEPARTMENT **A**  
ECONOMIC AND SCIENTIFIC POLICY

Economic and Monetary Affairs

Employment and Social Affairs

**Environment, Public Health  
and Food Safety**

Industry, Research and Energy

Internal Market and Consumer Protection



# Legal Implications of TTIP for the Acquis Communautaire in ENVI Relevant Sectors

STUDY





**DIRECTORATE GENERAL FOR INTERNAL POLICIES**  
**POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY**

# **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**

## **STUDY**

### **Abstract**

This study discusses the potential impact of the Transatlantic Trade and Investment Partnership agreement on the EU *acquis* in the areas of the environment and food safety. It recommends, in particular, that the European Parliament pay very close attention to the precise wording of provisions regarding the environment, food safety, and investment set out in the final text to ensure that both parties are able to maintain the environmental and consumer protection standards they deem appropriate, as provided for in the European Commission's negotiating mandate.

This document was requested by the European Parliament's Committee on the Environment, Public Health and Food Safety.

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## LIST OF ABBREVIATIONS

- BIT** Bilateral investment treaty
- CFI** Court of First Instance
- CFR** Code of Federal Regulations (US)
- CMO** Common Market Organisation
- CMR** Carcinogenic, mutagenic or toxic to reproduction
- CSR** Chemical safety report
- ECHA** European Chemicals Agency
- ECJ** European Court of Justice
- EFSA** European Food Safety Authority
- EPA** Environmental Protection Agency (US)
- ETS** Emissions trading scheme
- EU** European Union
- FDA** Food and Drug Administration (US)
- FFDCA** Federal Food, Drug, and Cosmetic Act (US)
- FOIA** Freedom of Information Act (US)
- FSIS** Food Safety and Inspection Service (US)
- FTA** Free trade agreement
- GATT** General Agreement on Tariffs and Trade
- GDP** Gross domestic product
- GMO** Genetically modified organism
- HACCP** Hazard Analysis and Critical Control Points
- ICAO** International Civil Aviation Organisation
- ICSID** International Center for Settlement of Investment Disputes

<b>ISDR</b>	Investor-state dispute resolution
<b>MoU</b>	Memorandum of Understanding
<b>NAFTA</b>	North American Free Trade Agreement
<b>NGO</b>	Non-governmental organisation
<b>NTB</b>	Non-tariff barrier to trade
<b>PBT</b>	Persistent, bioaccumulative and toxic
<b>PMN</b>	Pre-manufacture notification
<b>PPIA</b>	Poultry Products Inspection Act (US)
<b>PRT</b>	Pathogen reduction treatments
<b>REACH</b>	Registration, Evaluation, Authorisation and Restriction of Chemicals
<b>SPS</b>	Sanitary and phytosanitary
<b>SIA</b>	Sustainable impact assessment
<b>SVHC</b>	Substances of very high concern
<b>TFEU</b>	Treaty on the Functioning of the European Union
<b>TSCA</b>	Toxic Substances Control Act (US)
<b>TTIP</b>	Transatlantic Trade and Investment Partnership
<b>UNCITRAL</b>	UN Commission on International Trade Law
<b>UNCTAD</b>	United Nations Conference on Trade and Development
<b>UK</b>	United Kingdom
<b>US</b>	United States
<b>USDA</b>	United States Department of Agriculture
<b>vPvB</b>	Very persistent and very bioaccumulative
<b>WTO</b>	World Trade Organisation

## EXECUTIVE SUMMARY

The European Commission has recently initiated negotiations with the United States of America (US) regarding a proposed free trade agreement between the two parties, dubbed the “Transatlantic Trade and Investment Partnership” (TTIP). If successful, the economies covered by TTIP would account for nearly half of the global gross domestic product (GDP) and the standards set forth within it might become globally-accepted norms. Therefore, ensuring that the agreement upholds high standards for environmental protection, food safety is of the utmost importance. It is clear that the negotiations will focus on issues such as the harmonisation of rules and investment protection, among others. This has led to concerns, among non-governmental organisations (NGOs) and beyond, that TTIP may curb the regulatory freedom on either side and could lead to a downward harmonisation of environmental and food safety standards. Against this background, the purpose of this study is to discuss the potential impact of TTIP on the EU *acquis* in the areas of the environment and food safety.

The practical impact of a future TTIP on the EU *acquis* will depend, *inter alia*, on the legal effect of such a bilateral trade and investment agreement within the EU legal order and the ways it can be enforced judicially. In a first section, the study therefore discusses the legal effect of international trade and investment agreements in the EU legal order as well as dispute resolution mechanisms in international trade and investment agreements. While the EU obviously has an obligation to implement any international legal agreement it has ratified, the Court of Justice of the European Union (ECJ) has consistently held that international trade and investment agreements only have direct effect within the EU in very limited circumstances. Thus, in past ECJ cases, private companies have not normally been able to rely on e.g. World Trade Organisation (WTO) law for invalidating an EU action or claiming damages from the EU.

With regard to dispute resolution mechanisms outside the EU, the study observes that many bilateral investment treaties contain investor-state dispute resolution (ISDR) provisions besides inter-state dispute resolution provisions. ISDR provisions allow private actors, typically companies, who believe that a party to an investment agreement has violated the agreement, to bring claims against that party in a judicial forum outside national courts. In ISDR cases, investors most frequently seek monetary compensation for behaviour by the host state that negatively affected their business, including losses due to changes in government policies. If TTIP contains broadly worded investment protection clauses, ISDR could hamper the EU and Member States in efforts to establish regulations seeking to protect their citizens or the environment. Hence, if ISDR provisions are included in TTIP, the substantive obligations of TTIP will have to be reviewed very carefully, to assess their potential impact on the EU’s right to regulate.

In a second section, this study has identified a number of issues where regulations in the EU and US are substantially different and which may thus be influenced by a future TTIP:

- **Genetically Modified Organisms** (GMOs) have already been the topic of one WTO dispute between the US and the EU. Whereas the EU employs the precautionary principle and a thorough risk assessment process in determining which GMOs are allowed on the market, regulators in the US assume that GMOs are “substantially equivalent” to their non-GMO counterparts and allow them on the market without a distinct regulatory regime.



- **Chemical regulations** differ significantly between the US and the EU. While the EU's REACH framework requires all chemicals on the European market to be registered with the European Chemicals Agency, including the submission of safety data, US legislation only requires the submission of safety data in very specific circumstances and allows chemicals that were on the market prior to 1976 to remain on the market without any testing or registration requirement whatsoever. It is however possible that the TTIP will be an impetus for American legislators to strengthen their chemical regulation regime to align it better with REACH, an issue which has been pushed within Congress by members of both major parties since at least 2005.
- **Poultry pathogen reduction treatments** (PRTs), chemicals used to sanitize poultry intended for human consumption, are a controversial topic in trade between the EU and the US and have already been the source of bilateral and WTO dispute resolution processes. While both parties possess comprehensive regulations overseeing the production and processing of poultry, since 1997 the EU has held that only water may be used to wash poultry carcasses for sale on the European market, whereas the US allows its processors to use a number of different PRTs – including chlorine dioxide. The EU has upheld its standards in the interest of food safety, consumer confidence, and industry competitiveness. Meanwhile, these standards have resulted in a loss of hundreds of millions of dollars in lost US poultry exports, making them of likely interest to US negotiators.
- **Aviation emissions** are the source of an on-going dispute between the US and the EU, regarding the EU's approach to require international air travel originating or terminating in the EU to comply with the EU's emissions trading system (ETS) requirements. The US has no equivalent programme to regulate aviation emissions, even though this sector is among the fastest growing sources of greenhouse gasses. The EU has recently offered a compromise solution. The more important goal is the completion of a global, market-based instrument by the International Civil Aviation Organisation (ICAO) by 2016.

In conclusion, we recognize that the strongest action that the European Parliament could take to impact TTIP would be to not give its consent to the negotiated agreement, a route it has taken for other agreements in the past. Additionally, the European Parliament could play a role in increasing public awareness of TTIP negotiations and their impact and could stoke a political debate on relevant topics. We recommend that the European Parliament pay very close attention to the precise wording of provisions regarding the environment, food safety, and investments set out in the final text in order to ensure that both parties are able to maintain the environmental and consumer protection standards that they deem necessary and appropriate, as provided for in the European Commission's negotiating mandate.

## 1. INTRODUCTION

In February 2013, US and EU officials began the procedures necessary for initiating formal negotiations on a free trade agreement (FTA) dubbed the "Transatlantic Trade and Investment Partnership" (TTIP).<sup>2</sup> If it were to go into force, TTIP would encompass a combined 47% of global GDP and would be expected to increase the GDPs of the EU and the US by 0.5% and 0.4% respectively in absolute terms.

Both parties stated at some stage the aim of concluding the negotiations in 2014 already. However, many observers – and apparently also some trade officials<sup>3</sup> – see this timeline as ambitious and unrealistic in the light of experience with past trade negotiations. This expectation is lent additional substance by the fact that the planned October 2013 round of negotiations had to be cancelled due to the US government shutdown.<sup>4</sup>

The two sides are very close trading partners and have already eliminated many of the larger impediments to the flow of goods and services; they also provide a high level of legal certainty for investors and efficient judicial procedures. Indeed, the US has bilateral investment agreements with several EU Member States already.<sup>5</sup> It is noteworthy that these have been mainly concluded with Member States that joined the EU in 2004 or later. However, there has been so far no investment agreement with the EU, given that investment has only become an (exclusive) competence of the EU with the Lisbon Treaty.<sup>6</sup>

Given that most tariffs are already low between the trading partners, it is expected that the majority of gains of TTIP would come from the elimination of regulatory differences, some of which are estimated to inflict a cost on producers and importers equivalent to a 10-20% tariff.<sup>7</sup> Differences in regulations exist, among other, in the area of environmental legislation and trade sanitary and phytosanitary (SPS) measures, which address food product safety. While both the US and the EU have relatively high food safety standards, differences in their regulatory requirements can necessitate double-testing of some products, something which negotiators would like to eliminate. In addition, the harmonisation of other environmental as well as investment standards and requirements could make transatlantic trade easier and cheaper. Meanwhile, if harmonisation is structured to allow the lower of the two standards to be acceptable on both sides of the Atlantic or curbs the regulatory freedom on either side, TTIP may actually have a negative environmental impact. Indeed, such concerns have been raised by a number of non-governmental organisations (NGOs). Against this background, the purpose of this study is to discuss the potential impact of TTIP on the EU *acquis* in the areas of the environment and food safety.

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<sup>2</sup> European Commission: Recommendation for a Council Decision authorising the opening of negotiations on a comprehensive trade and investment agreement, called the Transatlantic Trade and Investment Partnership, between the European Union and the United States of America, [http://www.s2bnetwork.org/fileadmin/dateien/downloads/EU\\_Draft\\_Mandate\\_-\\_Inside\\_US\\_Trade.pdf](http://www.s2bnetwork.org/fileadmin/dateien/downloads/EU_Draft_Mandate_-_Inside_US_Trade.pdf)

<sup>3</sup> See White and Case, EU outlines preliminary goals in connection to first TTIP round, 17 July 2013, <http://www.whitecase.com/files/Publication/35f03363-f7bc-4c51-af9e-f1a24cb393cc/Presentation/PublicationAttachment/be813cc6-6448-49d9-82b3-044c60291fe4/alert-EU-outlines-preliminary-goals-in-connection-to-first-TTIP-round.pdf>

<sup>4</sup> BBC, US government shutdown halts EU free trade talks, 5 October 2013, <http://www.bbc.co.uk/news/world-asia-24407816>

<sup>5</sup> See the list of US bilateral investment treaties provided by the US Department of State at: <http://www.state.gov/e/eb/ifa/bit/117402.htm>.

<sup>6</sup> See Art. 207 TFEU. The status of the existing MS bilateral investment treaties is regulated in Regulation No 1219/2012 of 12 December 2012 establishing transitional arrangements for bilateral investment agreements between Member States and third countries. According to its Art. 3 bilateral investment treaties of the Member States that have been notified to the Commission may be maintained in force, until a bilateral investment agreement between the Union and the same third country enters into force.

<sup>7</sup> European Commission, European Union and United States to launch negotiations for a Transatlantic Trade and Investment Partnership, 13 February 2013, <http://trade.ec.europa.eu/doclib/press/index.cfm?id=869>

Negotiation documents on TTIP are, as normally in trade negotiations, not public. While the EU Commission is undertaking efforts to enhance transparency, e.g. by making a number of its initial positions papers public<sup>8</sup>, it is not possible to know precisely what position either delegation will take throughout the negotiations with regard to a particular topic and where compromise will be achievable. This makes it very hard to predict the content and impact of the resulting agreement and requires that this study rely upon the limited evidence available to evaluate possible topics of discussion in the negotiation process.

The European Commission's (leaked) draft negotiating mandate and its initial position papers shed some light on the intentions of negotiators involved with TTIP. The negotiating mandate itself makes references to sustainable development and the right of the EU and the US to regulate in accordance with the level of health, safety, consumer, labour and environmental protection each side deems appropriate; it states that parties will not encourage trade and investment by lowering e.g. environmental standards. In addition, the mandate states that the agreement will "include commitments by both Parties in terms of the labour and environmental aspects of trade and sustainable development".<sup>9</sup> The EU's accompanying impact assessment evaluates TTIP's potential impacts on both CO<sub>2</sub> emissions and natural resource use and concludes that changes in both of these figures is expected to be negligible (between -0.02% and +0.07% fluctuation in global CO<sub>2</sub> emissions; approximately +0.01% increase in resource use).<sup>10</sup> Food safety is not mentioned as an issue in the impact assessment.

Alternatively, recently finalised EU and US free trade agreements could be a source of insight into the intentions and priorities of negotiators on both sides (Schott and Cimino, 2013). Quite recently, both the US and the EU concluded separate FTAs with South Korea. Regarding environmental issues, the two agreements are rather dissimilar. The US agreement forbids the weakening of national environmental standards and allows for environmental disputes to be addressed in a dispute settlement mechanism, including the possibility of sanctions as recourse for violations. The EU's agreement is widely seen as providing comparatively weaker environmental protection as it does not allow use of the dispute resolution mechanism for environmental issues (Cooper et al., 2013; European Commission, 2010).

Many observers believe that TTIP is seen by negotiators as a tool to impact international trade more broadly, as well. It has been claimed that passing such an agreement could not only jumpstart the World Trade Organisation's (WTO) Doha Round of negotiations, but that it could provide a blueprint, designed in Washington and Brussels, for what free trade looks like moving forward (Mair and Mildner, 2013; Mildner and Schmucker, 2013). However, others believe that the agreement could actually derail further progress within the WTO (CESifo Group Munich, 2013) or even negatively impact countries that already have concluded FTAs with either the US or the EU (or both) (Berger and Brandi, 2013).

In any event, TTIP negotiations will have to be conducted taking into account the framework provided by WTO law, an organisation to which both the EU and the US are members. However, certain exceptions from WTO rules are allowed, according to Art. XXIV GATT, for free trade agreements concluded only between some WTO Members.

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<sup>8</sup> EU publishes initial TTIP Position Papers, 16 July 2013, <http://trade.ec.europa.eu/doclib/press/index.cfm?id=943>

<sup>9</sup> Council of the European Union, Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America, 17 June 2013, <http://www.s2bnetwork.org/fileadmin/dateien/downloads/EU-TTIP-Mandate-from-bfmtv-June17-2013.pdf>

<sup>10</sup> European Commission, Commission Staff Working Document: Impact Assessment Report on the Future of EU-US Trade Relations. Strasbourg, European Commission, [http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc\\_150759.pdf](http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150759.pdf)

The article is rather complex, and the details of its interpretation are disputed.<sup>11</sup> However, basically bilateral or regional free trade agreements must facilitate trade between the parties and must not raise additional trade barriers to third countries as compared to the situation before the conclusion of the free trade agreement. Moreover, the article also states that "substantially all trade" must be liberalised in such an agreement. Free trade agreements must also be notified to the WTO.

The purpose of this study is to discuss the potential impact of TTIP on the EU *acquis* in the areas of the environment and food safety. It should be noted that this study hence does not provide a full discussion of any environmental or food safety issues that could arise in the context of the TTIP negotiations. Notably, we do not discuss what opportunities TTIP might offer for both sides to agree on joint action in the field of the environment (e.g. harmonisation of technical standards for eco-friendly products). Moreover, other issues that could be of interest were outside the scope of this study (e.g. past experience with environmental exemption norms in international trade agreements or the overall anticipated effect of TTIP on the global environment).

The study is structured as follows: First (section 2) we discuss the legal effect of international trade and investment agreements of the EU within the EU legal order, which will influence the impact of a potential agreement on the EU legislative *acquis*. Furthermore, we describe dispute resolution within international investment treaties and in particular investor-state dispute resolution mechanisms and their potential impact on the regulatory freedom of the EU. We then (section 3) identify several policy areas where existing EU or US regulatory or policy approaches in the past created trade-related controversies or that observers have identified as being particularly relevant for future TTIP negotiations: the regulation of GMOs, treatment of poultry meat, toxic substances and emissions trading in the aviation sector. For each of these areas, we briefly present the current major differences between the two legal orders. The study concludes with recommendations directed at the European Parliament.

### **Talking and thinking about the environmental impact of trade on the environment**

Negotiations on TTIP are not the first international trade and investment negotiations that have led to questions about the impact of international trade on the environment. For example, the establishment of the World Trade Organisation (WTO) in 1995 triggered a sizeable "trade and environment" debate. Generally, trade and thus also international trade agreements aimed at increasing cross-border trade are not necessarily either bad or good for the environment. The picture is mostly rather complex.

Generally, a number of trajectories for the environmental impact of trade have been identified (Frankel, 2008; Boyle, 2009):

- Trade itself creates emissions and uses resources for the physical transport of goods; with increased trade, transport-induced pollution and resource use will increase.

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<sup>11</sup> Indeed, WTO Members adopted in the course of the Uruguay Round of negotiations a separate „Understanding“ on this article, an unusual measure in the WTO context, see: [http://www.wto.org/english/tratop\\_e/region\\_e/reqatt\\_e.htm#understanding](http://www.wto.org/english/tratop_e/region_e/reqatt_e.htm#understanding)

- There may be increased income from increased trade, which may lead to changes in the environmental situation in a country. A common finding is the so-called environmental Kuznets Curve. At early stages of economic development, increased, trade-induced economic activity has a negative impact on the environment. However, after a critical threshold level of economic development is reached, further growth tends to bring an improvement in the environment (e.g. because of increased demands for a clean environment).
- Moreover, openness to trade might encourage some countries, so called “pollution havens”, to specialize in dirtier activities, and to export their products to others with higher environmental standards. From this perspective, trade liberalisation would lead to a re-distribution of pollution across countries, rather than changing the overall average.
- On the other hand, trade may also lead to the wider diffusion of environmentally friendly technologies as well as greater specialisation which may lead to efficiency gains and thus less resource-use.
- Finally, an important aspect of international economic agreements is the extent to which they restrict the freedom of the parties involved to take future regulatory action and/or a “race to the bottom” in environmental standards.

How the impact of a trade and agreement investment looks in a given country at a given time is very much case specific.

Assessing such impact is also methodologically complex. Classic impact assessments, such as the one conducted by the EU Commission on TTIP already, are mainly focused on the economic impact of trade agreements. They use measures such as expected changes in GDP. However, these measures are often highly questionable from an environmental point of view. For example, the European Parliament adopted in 2011 a resolution which highlights the shortcomings of GDP for measuring, for example, progress towards greater environmental sustainability and resource efficiency.<sup>12</sup>

In the EU, trade agreements are also subject to sustainable impact assessments (SIA), which seek to predict the impact of such agreements on environmental quality, biological diversity and other natural resources, among other.<sup>13</sup> The appropriate methodology for SIA is, however, also controversial;<sup>14</sup> moreover, it is sometimes not clear to which extent the results of a SIA effectively influence negotiations.

Finally, another point should be made about the language used when talking and thinking about international trade. In this context, terms like “non-tariff barriers to trade” are often used. However, from an environmental point of view, a “non-tariff barrier to trade” may be a perfectly legitimate and much needed environmental regulation. Thus, wherever possible, neutral terms should be used.

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<sup>12</sup> European Parliament resolution of 8 June 2011 on GDP and beyond – Measuring progress in a changing world ([2010/2088\(INI\)](#))

<sup>13</sup> European Commission, Sustainability Impact Assessments, [http://ec.europa.eu/trade/policy/policy-making/analysis/sustainability-impact-assessments/index\\_en.htm](http://ec.europa.eu/trade/policy/policy-making/analysis/sustainability-impact-assessments/index_en.htm)

<sup>14</sup> An overview is provided by (Görlach et al., 2005).

## 2. THE LEGAL EFFECT OF INTERNATIONAL TRADE AND INVESTMENT AGREEMENTS IN THE EU LEGAL ORDER

### KEY FINDINGS

- According to the ECJ jurisprudence, international trade and investment agreements ratified by the EU generally have no direct effect on the EU legal order, i.e. complainants cannot rely on the respective agreement before a Member State's courts and or the ECJ for invalidating EU actions or claiming damages.
- The ECJ makes an exception to the above principle if the EU has intended to implement a particular international trade-related obligation in EU law, or where the EU measure refers expressly to the precise provisions of an international legal agreement (e.g. in the case of EU anti-dumping provisions). In such cases, the ECJ reviews the legality of the Community measures in question in the light of the international trade rules.
- Many bilateral investment treaties contain investor-state dispute resolution (ISDR) provisions besides inter-state dispute resolutions provisions. ISDR provisions allow private investors to bring claims against a foreign state party to an investment treaty before an international arbitration tribunal, on the basis of an alleged violation of the investment treaty. This is a mechanism largely unknown in international law outside investment law.
- There are widely diverging views on ISDR. The corporate sector generally calls for the inclusion of such a mechanism in investment treaties, arguing that it provides incentives for investment. By contrast NGOs and a number of states are increasingly concerned that ISDR (or the threat thereof) may unduly restrict the regulatory freedom of states and lead to claims for substantial amounts of damage against states taking environmental measures.
- On the basis of past experience, there is a real risk of a negative impact of ISDR provisions in combination with broadly-worded substantive provisions on investment protection in an eventual TTIP on the regulatory freedom of the EU or Member States' space for acting in the public interest, including in the area of the environment and food safety. It is also doubtful whether there is a need for such clauses in an agreement between two highly evolved rule-of-law legal orders.

Generally, international law, including international agreements – whether multilateral like WTO law or bilateral like TTIP – and national/EU law are separate legal orders. The legal effect that an international treaty has in a given national legal order is determined by that legal order and not by international law.<sup>15</sup> In principle, for international legal agreements to have legal effect within the EU legal order, they need to be implemented within the EU, normally by amending or adopting EU secondary legislation. Once such legislation is in place, it has the same legal effect as EU law that is purely domestic in origin. The case that the EU properly implements international agreements that it has ratified is unproblematic – the EU acts in line with its international legal obligations.

However, there may be situations in which the EU has ratified an international trade and investment agreement, but not implemented it domestically or where there is a controversy on whether EU law is in line with the obligations contained in the agreement.

<sup>15</sup> Theoretically, an international legal agreement may contain clauses on what legal effect the parties give a certain provision in their respective legal orders. However, such clauses are rather uncommon. For one example, see Art. 54(1) of the ICSID Convention, mentioned below in Section 4.

In such cases, companies or individuals or even EU Member States who consider that they are losing some benefit that the agreement would otherwise confer them or the other state party to the agreement may wish to take the issue to a judicial body. The practical impact of a future TTIP on the EU *acquis* will depend, *inter alia*, on the legal effect of such a bilateral trade and investment agreement within the EU legal order and the way it can be enforced judicially.

This section hence deals with the following issues. First (section 2.1), we discuss the legal effect of international trade and investment agreements within the EU legal order. This influences, whether EU or US companies can invoke the rules of an international trade and investment agreement before the ECJ to invalidate EU legislation or other actions and whether they can claim damages from the EU if the EU fails to bring its legal order into compliance with rules contained in TTIP. However, the practical impact of an international trade and investment agreement depends not only on the extent to which the parties implement it and what legal effect the provisions have in the domestic legal orders of the states involved, but also on the extent to which they can rely on additional mechanisms to enforce it. Thus, most international trade and investment agreements include mechanisms for dispute resolution. Such mechanisms and their potential effect on the EU environmental *acquis* are discussed in section 2.2. A focus is on so called investor-states dispute resolution and its impact on environmental regulation.

## 2.1. The direct effect of trade and investment agreements in the EU legal order

One avenue that companies may wish to pursue in order to seek remedies for an alleged failure of the EU to implement an agreement it has concluded, is raising this issue before Member States' courts or the ECJ. In fact, the ECJ has in the past had to decide in several such cases on whether an international trade/investment agreement concluded and ratified by the EU has direct effect within the EU legal order, i.e. whether complainants can rely on the respective agreement before a Member State's courts and in particular whether the ECJ can invalidate EU actions.<sup>16</sup> The ECJ has assessed the direct legal effect of trade/investment agreements in a series of cases, mostly relating to GATT/WTO law.<sup>17</sup>

The ECJ position that – with some variations – has been re-iterated until today is that a plaintiff can rely on international legal provisions that are binding on the EU if they are “capable of conferring rights on citizens of the Community”.<sup>18</sup> The ECJ ascertains whether this is the case by looking at the subject matter and purpose of the respective rules.<sup>19</sup> In some cases, it also looked at whether the relevant international legal provision involved an “unconditional and precise obligation”.<sup>20</sup>

With regard to multilateral trade agreements, the WTO agreements, the ECJ holds the position that they have no direct effect as they are based on negotiations and are characterized by a relative flexibility of their provisions.<sup>21</sup>

<sup>16</sup> In EU law, the term “direct effect” gained prominence after the *Van Gend en Loos* case (Case 26/62) in which the ECJ famously decided that a certain provision of the EC Treaty could be used as a basis for a lawsuit by private plaintiffs in a Member State court and thus had „direct effect”.

<sup>17</sup> For purposes of this study only a summary of the case law can be presented. For a comprehensive overview see (Errico, 2011).

<sup>18</sup> ECJ, Judgment of 12 December 1972, *International Fruit Company NV*, Joined Cases C-21 to 24/72, para. 8.

<sup>19</sup> See for example ECJ, Judgment of 23 November 1999, *Portuguese Republic v. Council of the European Union*, C-149/96, para. 41.

<sup>20</sup> ECJ, Judgment of 26 October 1982, *Hauptzollamt v. Kupferberg*, C-104/81, para. 20; ECJ, Judgment of 9 September 2008, *FIAMM et al.*, para. 110.

<sup>21</sup> The relevant case under the old GATT was ECJ, Judgment of 12 December 1972, *International Fruit Company NV*, Joined Cases C-21 to 24/72, paras. 20ff. The relevant case after the establishment of the WTO

Conferring direct effect to WTO law within the EU legal order would, according to ECJ, deprive the executive and legislative branches of the freedom to negotiate and might also lead to imbalances in the relation with trading partners whose legal orders do not confer direct effect to WTO law. This line of reasoning has been described as “settled case-law” by the ECJ itself.<sup>22</sup>

There are fewer cases concerning bilateral agreements of the EU. In one early case, the ECJ decided that a clause in an agreement between the EU and Portugal (then not an EU Member State) prohibiting fiscal measures discriminating against imported as compared to domestic like products, had direct effect within the EU legal order.<sup>23</sup> However, this case seems to represent an exception in ECJ case law where international trade law has generally not been accorded direct effect.

The ECJ has also extended its findings on the lack of direct effect of WTO law to claims for damages by individuals or companies who feel they are negatively affected by the EU’s failure to act in compliance with trade and investment agreements it has ratified. The legal starting point for such claims is Art. 340 (2) Treaty on the Functioning of the European Union (TFEU). According to this norm, the EU has to make good any damages caused by its institutions or servants in the performance of their duties (outside of contractual obligations). On this basis, some companies had sought damages from the EU for failure to bring EU law into compliance with WTO law. In two of these cases, the WTO Dispute Settlement Body had previously explicitly stated that the EU was acting inconsistently with WTO law.<sup>24</sup> Following these findings and subsequent counter-measures by the US which affected EU imports to the US in various sectors, some companies had seen their business activities harmed by the EU behaviour and consequently claimed damages from the EU. In the first of these cases, *Biret*, the EU General Court (then Court of First Instance, CFI) did not award damages, based on the ECJ’s reasoning in the *Portugal* case to the end that WTO law does not have direct effect in EU law.<sup>25</sup> In the second case, *FIAMM*, the ECJ explicitly reaffirmed the position that plaintiffs could not rely on WTO law or WTO dispute settlement decisions before the ECJ to claim the invalidity of EU law or damages.<sup>26</sup>

However, the ECJ has accepted the so called *Nakajima* and *Fediol* exceptions to the above rules. In these cases, the ECJ recognised that a complainant could invoke WTO law to invalidate EU law if the relevant norms of EU law had been adopted specifically to implement WTO law.<sup>27</sup> The legislation under discussion was the EU anti-dumping regulation which specifically serves to implement the WTO Anti-Dumping Agreement.

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in 1995 is ECJ, Judgment of 23 November 1999, Portuguese Republic v. Council of the European Union, C-149/96, paras. 34ff

<sup>22</sup> See ECJ, Judgment of 1 March 2005, Léon van Parys NV v. Belgisch Interventie- en Resitutiebureau (BIRB), C-377/02, para. 39.

<sup>23</sup> ECJ, Judgment of 26 October 1982, Hauptzollamt v. Kupferberg, C-104/81.

<sup>24</sup> The cases were European Communities — Measures Concerning Meat and Meat Products (Hormones), [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds26\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds26_e.htm) and European Communities — Regime for the Importation, Sale and Distribution of Bananas, [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds27\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds27_e.htm)

<sup>25</sup> Court of First Instance, Judgment of 11 January 2002, Biret International v. Council of the European Union, T-174/00, paras. 60ff. The ECJ in *Biret* upheld the General Court’s decision, albeit on the basis of the specific factual circumstances of the case, rather than overarching considerations of the character of WTO law and its legal effect within the EU; see ECJ, Judgment of 30 September 2003, Case C-04/02, Etablissements Biret et Cie SA.

<sup>26</sup> ECJ, Judgment of 9 September 2008, FIAMM et al., Joined Cases C-120/06 P and C-121/06, paras. 110ff.

<sup>27</sup> ECJ, Judgment of 7 May 1991, *Nakajima All Precision v. Council of the European Communities*, C-69/89, paras.29ff ; ECJ, Judgment of 22 June 1989, *EEC Seed Crushers' and Oil Processors' Federation (Fediol) v. Commission of the European Communities*, C-70/87, paras. 18ff.



Thus, in the words of the ECJ: "It is only where the Community has intended to implement a particular obligation assumed in the context of the WTO, or where the Community measure refers expressly to the precise provisions of the WTO agreements, that it is for the Court to review the legality of the Community measures in question in the light of the WTO rules."<sup>28</sup>

While the above decisions have mostly been taken on WTO law, i.e. multilateral trade law, there is no reason to assume that the ECJ's position on a comprehensive bilateral trade and investment agreement would be any different, even though no certain predictions can be made on the matter. All in all, there are thus only very specific situations – the EU has intended to implement a particular obligation assumed in the context of TTIP or an EU measure refers expressly to a TTIP provision – that TTIP would be likely to have direct effect in EU law.

## **2.2. Dispute resolution in bilateral trade and investment agreements**

Disputes relating to the interpretation and compliance with a trade and investment agreement may, however, not only be brought before national courts, but also be addressed by judicial institutions at the international level. With regard to dispute resolution in bilateral trade and investment agreements, two different mechanisms must be distinguished:

First, there are mechanisms allowing the state parties to the disputes to settle disputes amongst themselves, when one party is of the view that the other one has not complied with its obligations (so called inter-state dispute settlement). For example, in the WTO such inter-state disputes are handled by the WTO dispute settlement system. From an environmental point of view, such mechanisms do not raise particular concerns – if the substantive provisions of the treaty are "environment-friendly", adjudicating them is likely to lead to an environmentally-friendly outcome as well. In fact, inter-state dispute resolution can even be beneficial if the respective bilateral agreement contains ambitious environmental norms whose violation could then become subject of an international judicial dispute.

The second mechanism for dispute resolution, contained regularly in international investment agreements, is investor-state dispute resolution (ISDR). Related rules provide for the opportunity of private actors, typically companies, who hold the view that a state party to the respective investment agreement does not act in line with the agreements, to bring claims against that party in a judicial forum. Thus, through ISDR foreign investors are provided with an additional tool for seeking protection of their investments and business expectations in addition to whatever judicial mechanisms already exist in the legal systems of the respective states. This is why the observation is sometimes made that ISDR provisions offer stronger protection to foreign investors than domestic ones. Various concerns have been voiced over the impact of ISDR on the freedom of states to take measures to protect the environment or public health or to pursue other public policy goals (see next section for a more detailed discussion).

The most "judicialised" form of ISDR is arbitration, a form of dispute resolution outside of courts, where the parties to a dispute refer it to one or more persons who judge the matter by existing legal rules and by whose decision the parties to the dispute agree to be bound.

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<sup>28</sup> See ECJ, Judgment of 1 March 2005, *Léon van Parys NV v. Belgisch Interventie- en Resitutiebureau (BIRB)*, C-377/02, para. 40; ECJ, Judgment of the Court of 27 September 2007, *Ikea v. Commissioners of Customs & Excise*, C – 351/04, para. 30.

The forum most frequently chosen for investor-state arbitration in bilateral investment treaties (BITs) is the World Bank's International Centre for the Settlement of Investment Disputes (ICSID)<sup>29</sup> even though other fora exist for such arbitration.

Arbitrators in ICSID cases are appointed for the specific case; they will "judge" the dispute on the basis of rules of law as agreed by the parties (e.g. an investment agreement), or if there is no such agreement the law of the state involved and pertinent rules of international law. Arbitral awards and other documents are not normally public, but are sometimes published with the consent of the parties involved. In ICSID proceedings, investors most frequently seek monetary compensation for the unlawful behaviour of the host state. If a claim is considered justified, the award will specify an amount of damages to be paid to the investor; the amounts can sometimes be very high, reaching hundreds of millions of US dollars (Gaukrodger and Gordon, 2012: 7). An ICSID decision awarding monetary damages is equivalent to a court judgment in all of the ICSID Contracting States, i.e. directly executable.<sup>30</sup>

In the context of TTIP, using ICSID as a forum may be problematic from a legal point of view: The use of the ICSID arbitration procedure is open, according to Art. 1(2), 25(1) of the ICSID Convention, to Contracting States of that Convention and their nationals. However, as the EU is not a state, it does not currently fulfil the conditions for acceding to the ICSID Convention set forth in Art. 67 ICSID Convention. However, the EU Member States have ratified the ICSID Convention; thus, investors could initiate ICSID arbitration against them, rather than against the EU. Alternatively, the US and EU could agree on using a different institution or set of rules for ISDR under TTIP.

### **Investor-state dispute resolution: a risk to the environment?**

Arguments made in favour of including investor-state dispute resolution (ISDR) in bilateral investment agreements include the following:

- Investors should not depend on the political will of their home states to support them in inter-state dispute resolution. Sometimes the threat of an investment dispute may be sufficient to amicably settle a dispute.
- For states, engaging in inter-state dispute resolution may often be unattractive, because it may lead to irritations among trade partners. The same is not true for investor-state dispute resolution, because it is private companies that initiate such dispute resolution.
- If the EU (or a state) initiates inter-state dispute resolution, it has to bear the financial and administrative burden of the proceedings. If a private actor initiates such proceedings, these costs do not have to be covered by the EU.
- Moreover, it is hoped that taking such disputes out of the realm of the state against which claims are brought would ensure the neutrality of the proceedings.

An additional rationale induced for ISDR provisions in particular with regard to investment agreements involving developing countries, is that in some countries domestic legal systems are not very effective, swift or transparent, and hence investors need to be given the option to resort to a different legal forum. All in all, it is hoped that such provisions could attract investments, even in countries with weak governance and judicial systems.<sup>31</sup>

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<sup>29</sup> According to UNCTAD figures, there have been so far over 500 known investor states dispute resolution cases, of which more than 300 were settled using ICSID, and another 130 using the United Nations Commission On International Trade Law (UNCITRAL) Rules (UNCTAD, 2013: 110).

<sup>30</sup> See Art. 54(1) ICSID Convention, online at [https://icsid.worldbank.org/ICSID/StaticFiles/basicdoc/CRR\\_English-final.pdf](https://icsid.worldbank.org/ICSID/StaticFiles/basicdoc/CRR_English-final.pdf)

<sup>31</sup> For a discussion of some of these arguments: (Gaukrodger and Gordon, 2012: 13).

In light of these arguments, the corporate sector is in favour of the inclusion of ISDR clause in international investment agreements (see for a summary of various positions on TTIP from the business community Annex 1). ISDR provisions have been widely included in bilateral investment treaties, and a few multilateral treaties<sup>32</sup>, showing that many states also consider them beneficial. Notably, the 2012 US model BIT<sup>33</sup> contains provisions on ISDR that in some respects seek to improve existing rules/models e.g. in the area of transparency. The EU has no similar model BIT currently. However, according to some reports the EU Commission circulated a draft document among Member States in 2012 detailing the ISDR provisions it will seek in future EU investment agreements.<sup>34</sup> According to some observers, the EU draft has some similarities with the US model BIT (e.g. on transparency), but there are also some differences that would have to be overcome in TTIP negotiations.<sup>35</sup> The TTIP negotiating mandate for the Commission specifies a number of conditions which would have to be satisfied for the EU to agree on ISDR provisions in TTIP.<sup>36</sup>

Generally, there have been more and more investor-state disputes, with the total of known cases exceeding 500, of which almost 60 were initiated in 2012. The latter concerned “a broad range of government measures, including changes to domestic regulatory frameworks (with respect to gas, nuclear energy, the marketing of gold, and currency regulations), as well as measures relating to revocation of licences (in the mining, telecommunications and tourism sectors). Investors also took action on the grounds of alleged breaches of investment contracts; alleged irregularities in public tenders; withdrawals of previously granted subsidies (in the solar energy sector); and direct expropriations of investments” (UNCTAD, 2013: 110).

However, numerous concerns have also been voiced over the impact of ISDR on, *inter alia*, environmental and health regulation, public services, and sustainable development at large. NGOs have referred to ISDR as the “world’s worst judicial system”<sup>37</sup> or “going to court with the devil in hell” (Corporate Europe Observatory and Transnational Institute, 2012: 11). However, the growing criticism does not only come from NGOs. Several states have in recent years publicly announced that they would not include any further ISDR clauses in their bilateral trade and investment agreements. For example, the Australian government adopted a policy not to include ISDR in future investment treaties into which Australia enters.<sup>38</sup> It states that the Australian government “does not support provisions that would confer greater legal rights on foreign businesses than those available to domestic businesses.

<sup>32</sup> Important examples are the Energy Charter Treaty (ECT) and the North American Free Trade Agreement (NAFTA).

<sup>33</sup> Online at <http://www.state.gov/e/eb/ifa/bit/index.htm>, see section B.

<sup>34</sup> Inside US Trade, EU Draft Text On ISDS Contains Similarities, Differences To U.S. Approach, 3 April 2013, <http://insidetrade.com/Inside-Trade-General/Public-Content-World-Trade-Online/eu-draft-text-on-isds-contains-similarities-differences-to-us-approach/menu-id-896.html>

<sup>35</sup> Inside US Trade, EU Draft Text on ISDS Contains Similarities, Differences To U.S. Approach, 3 April 2013, <http://insidetrade.com/Inside-Trade-General/Public-Content-World-Trade-Online/eu-draft-text-on-isds-contains-similarities-differences-to-us-approach/menu-id-896.html>. On the Commission draft see generally also Nathalie Bernasconi-Osterwalder, Analysis of the European Commission’s Draft Text on Investor-State Dispute Settlement for EU Agreements, 19 July 2012, <http://www.iisd.org/itn/2012/07/19/analysis-of-the-european-commissions-draft-text-on-investor-state-dispute-settlement-for-eu-agreements/>, describing it as a step in the right direction, but not sufficient yet.

<sup>36</sup> Council of the European Union, Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America, 17 June 2013, <http://www.s2bnetwork.org/fileadmin/dateien/downloads/EU-TTIP-Mandate-from-bfmtv-June17-2013.pdf>, para. 22f.

<sup>37</sup> South News No. 36, 30 July 2013, <http://us5.campaign-archive2.com/?u=fa9cf38799136b5660f367ba6&id=9ded86dbd2>

<sup>38</sup> Australian Government, Department of Foreign Affairs and Trade, Trade Policy Statement, April 2011, <http://www.dfat.gov.au/publications/trade/trading-our-way-to-more-jobs-and-prosperity.html>

Nor will the Government support provisions that would constrain the ability of Australian governments to make laws on social, environmental and economic matters in circumstances where those laws do not discriminate between domestic and foreign businesses.” Various developing countries have adopted a similar stance. For example Bolivia and Ecuador resigned in recent years from the ICSID Convention, in an attempt to prevent ICSID arbitration against them.<sup>39</sup> Other states, e.g. Brazil, have traditionally been reluctant to include related clauses in their international agreements (Gaukrodger and Gordon, 2012: 7). The United Nations Conference on Trade and Development (UNCTAD) in its 2013 Investment Report points to concerns over the legitimacy of private individuals judging the actions of sovereign governments, the transparency of proceedings, the consistency of the case law, the lack of possibility for reversing erroneous decisions, arbitrators’ impartiality and neutrality, and the high costs<sup>40</sup> of such proceedings (which a state may have to bear, even if it wins the case) (UNCTAD, 2013: 112).

While we could not find a research paper systematically and specifically surveying environment-related investor-state arbitration cases<sup>41</sup>, some cases where private companies used ISDR provisions in investment treaties to complain over domestic environmental or health regulation are the following:

- In a 1998 NAFTA/UNCITRAL case, a US-owned company sued Canada over legislation prohibiting inter-provincial trade in certain environmentally harmful fuel additives that the company produced.<sup>42</sup> After the arbitration tribunal had found it had jurisdiction to hear the case, the parties settled the case with Canada paying the company compensation and reversing the ban (Philippe Sands, 2008: 8).
- In a 2000 NAFTA/ICSID case, a US company claimed compensation from Mexico for its failure to grant a construction permit for a toxic landfill site already in operation in an area which was later declared a natural preservation site. The arbitration tribunal considered Mexico’s behaviour to be an expropriation and awarded more than 16 million US dollars in damages to the company.<sup>43</sup>
- In a 2003 ICSID case, a Spanish company sued Mexico under an investment treaty concluded between Spain and Mexico for not renewing the license for a landfill site, which was, *inter alia*, due to environmental and health concerns as well as popular opposition to the site. The arbitrators found a violation of the investment agreement’s clauses on “fair and equitable treatment” and expropriation and awarded damages to the Spanish company.<sup>44</sup>

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<sup>39</sup> (UNCTAD, 2010) - The Note also discusses the somewhat unclear legal consequences of such a step.

<sup>40</sup> The average costs for arbitrators and lawyers in case are estimated at 8 million US \$ by (UNCTAD, 2013: 112).

<sup>41</sup> However, for studies discussing some related issues see (OECD, 2004; Nikièma, 2012).

<sup>42</sup> Award on Jurisdiction in the case Ethyl Corporation v. The Government Of Canada 24 June 1998, 38 I.L.M. 708 (1999)

<sup>43</sup> Award in the case Metalclad Corporation v. The United Mexican States, CASE No. ARB(AF)/97/1, 30 August 2000, [https://icsid.worldbank.org/ICSID/FrontServlet?requestType=CasesRH&actionVal=showDoc&docId=DC542\\_En&caseId=C155](https://icsid.worldbank.org/ICSID/FrontServlet?requestType=CasesRH&actionVal=showDoc&docId=DC542_En&caseId=C155)

<sup>44</sup> Award in the case Técnicas Medioambientales Tecmed S.A. v. The United Mexican States, Case No. ARB (AF)/00/2, 29 May 2003, [https://icsid.worldbank.org/ICSID/FrontServlet?requestType=CasesRH&actionVal=showDoc&docId=DC602\\_En&caseId=C186](https://icsid.worldbank.org/ICSID/FrontServlet?requestType=CasesRH&actionVal=showDoc&docId=DC602_En&caseId=C186)

- In an on-going ICSID arbitration, the Swedish energy company Vattenfall filed a request for arbitration against Germany under the Energy Charter Treaty, because of Germany's decision to phase out nuclear energy. The company is expected to claim up to 700 million Euros in compensation for the closure of two of its nuclear power plants.<sup>45</sup>

For an investor to win a case, the respective investment agreement must obviously contain substantive provisions on which the investor's claims can be based. Generally, the arbitration decisions in investment cases adopted so far are not a consistent body of law, but indeed very much case-specific. Thus, two tribunals may interpret a similar term rather differently, even though tribunals sometimes include references to prior arbitrations awards.

Nonetheless, it can be observed that clauses protecting investors against expropriation have tended to prove "risky" with regard to governments' right to regulate, in particular in developing countries where governments do not necessarily have sufficient funds to compensate investors. In particular, the concept of "indirect expropriation", i.e. an action or conduct, which does not explicitly serve the purpose of depriving an investor of rights or assets, but actually has that effect, might pose obstacles for environmental measures.<sup>46</sup> A perceived negative impact on investments may result, *inter alia*, from measures that a state takes to regulate economic activities within its territory without that regulation being specifically targeted at investment (e.g. environmental regulation). A similarly problematic legal concept is "fair and equitable treatment" often contained in investment treaties. However, the Commission's negotiation mandate mentions as an objective for the TTIP negotiations including provisions on both "indirect expropriation" and "fair and equitable treatment".<sup>47</sup> Generally, the interpretation of existing treaty language in awards issued by international arbitrators against states has been criticised as "expansive" in a 2010 statement by a considerable number of law professors who were concerned with the current status of the international investment regime.<sup>48</sup>

In sum, there is a real risk of a negative impact of ISDR provisions in combination with broadly-worded substantive provisions on investment protection in an eventual TTIP on the regulatory freedom of the EU or Member States' space for acting in the public interest, including in the area of the environment. For avoiding such a negative impact, there are various avenues: First, ISDR provisions could be avoided altogether, or at least the exhaustion of domestic remedies could be made a pre-condition for using ISDR<sup>49</sup>. A very good point can be made that such provisions are not needed in the relationship between two trading partners with highly evolved, efficient, and impartial rule-of-law judicial systems where foreign investors can seek protection under the domestic legal systems in a similar manner to domestic investors without any risk of being treated unfairly. Second, ISDR provisions could be included that remedy some of the shortcomings of existing rules and systems.

<sup>45</sup> The documents relating to the case are not public. For a summary, see (Bernasconi-Osterwalder and Hoffmann, 2012). For an overview of the ICSID proceedings, see <https://icsid.worldbank.org/ICSID/FrontServlet>

<sup>46</sup> One of the problems with the term "expropriation" used in international investment law is precisely its unclear definition, see (Nikièma, 2012).

<sup>47</sup> Council of the European Union, Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America, 17 June 2013, <http://www.s2bnetwork.org/fileadmin/dateien/downloads/EU-TTIP-Mandate-from-bfmtv-June17-2013.pdf>, para. 23.

<sup>48</sup> Public statement on the international investment regime, 31 August 2010, <http://www.osgoode.yorku.ca/public-statement/documents/Public%20Statement%20%28June%202011%29.pdf>, para. 5.

<sup>49</sup> Requirement of recourse to domestic administrative or judicial remedies are relatively rare in investment treaties (Gaukrodger and Gordon, 2012: 27)

Third, if ISDR provisions are included in TTIP with a view to the potential benefits to investors as described above, the substantive provisions of the agreement should be worded in a way to ensure that the right of the parties to regulate is not affected. Making concrete suggestions to this end is beyond the scope of this study;<sup>50</sup> however, existing interpretations of e.g. clauses on expropriation and the tendency of such clauses being interpreted rather broadly and in an investment-friendly manner in international arbitral awards should be taken in account. Generally, precisely defining such terms and clear language to the end that non-discriminatory regulatory measures taken for environmental purposes are not to be considered a violation of a future TTIP are recommendable.

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<sup>50</sup> See for suggestions for example (Nikièma, 2012).

### 3. POLICY AREAS OF RELEVANCE – MAIN DIFFERENCES

#### KEY FINDINGS

- There are remarkable differences in the depth and stringency of regulation applied in the EU and the US in the four regulatory fields discussed here – genetically modified organisms, substances to treat poultry, chemicals, and emissions from aviation. In only one of these cases – emissions from aviation, a compromise solution seems close.
- Overall, a pattern is apparent wherein the US have chosen to either not acknowledge risks to the environment and human health recognised by the EU, or to address such risks in ways which markedly differ from the approach chosen in Europe, for instance by merely promulgating voluntary guidelines rather than mandatory requirements. For the case studies assessed in this section, it can therefore be safely affirmed that the regulatory intensity in the EU is higher than in the US, with the private sector facing fewer requirements and enjoying significantly greater flexibility in the US.
- Many existing trade and investment agreements are rather general in approach; for example they may contain a general commitment to regulatory convergence and procedures for attaining such regulatory convergence (e.g. by establishing a committee to that end). It seems therefore unlikely that any of the parties would make specific commitments to revise a specific legal act in TTIP.

#### 3.1. Selecting policy areas

In the following, we present policy areas that are part of the EU environmental *acquis* on which TTIP could have an impact. As mentioned in the introduction, it is, at the time of writing of this study, not clear which specific areas or clauses will be included in TTIP.

As it is not possible within the scope of this study to undertake a comprehensive across-the-board comparison of environmental and food safety regulations in both the US and the EU, we discuss in this section a limited number of areas that seem to be particularly likely candidates for the negotiations. The areas have been identified using the following sources:

- dispute settlement procedures at the WTO where the EU and US were on opposing sides, either as parties or as third parties, with a view to disputes involving environmental or food safety issues, as well as one prominent environment-related case recently brought by US companies before a UK Court which then referred it to the ECJ.
- EU and US Trade Policy Reviews at the WTO, including written documentation showing concerns that the respective party has raised over the environmental or food safety regulations of the other side.
- publications and statements by various organisations, including in particular environmental NGOs, on a potential negative environmental impact of TTIP as well as positions by the corporate sector on both sides of the Atlantic.
- a limited literature review on regulatory differences between the EU/US on environmental matters and in the area of food safety regulations.

Each of these aspects is discussed more in depth in Annex 1.

On this basis, we have identified the following areas where there is particular potential for controversy:

- GMO regulation which is mentioned in many publications as being controversial and has also been the subject of a WTO dispute.
- Regulation of toxic substances, an issue mentioned by many observers as controversial issue and also raised as problematic by the US during the WTO's review of the EU's trade policy.
- Regulation of the treatment of poultry, where perceptions of which processing options are safe have differed across the Atlantic, resulting in an import ban in the EU as well as the initiation of WTO dispute settlement proceedings by the US.
- Inclusion of the aviation sector in EU emissions trading, where the unilateral extension by the EU of its emissions trading system to flights coming from and departing to the US has led to a transatlantic diplomatic impasse and a legal case before the ECJ.

We have chosen not to analyse further the hormone-treated beef issue, as this controversy can be regarded as settled: In May 2009, the EU and the US signed a Memorandum of Understanding (MoU) "regarding the importation of beef from animals not treated with certain growth-promoting hormones and increased duties applied by the United States to certain products of the European Communities", which they notified the WTO of in September of that same year. Based on this MoU, which established a process in several steps, the EU increased its duty-free import quotas for hormone-free beef (High Quality Beef) through successive Regulations,<sup>51</sup> and, in exchange, the US gradually lifted its sanctions.

Generally, it should be noted that many existing trade and investment agreements are rather general in approach; for example they may contain a general commitment to regulatory convergence and procedures for attaining such regulatory convergence (e.g. by establishing a committee to that end).<sup>52</sup> It therefore seems unlikely that any of the areas discussed above is going to be included in the agreement as such or that any of the parties would make specific commitments to revise a specific legal act in TTIP.

In the following, we briefly assess the main differences between the EU and US legislation in the identified areas. A more in-depth description of the regulation on either side of the Atlantic in each of these fields is contained in Annex 2.

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<sup>51</sup> Council Regulation No 617/2009 of 13 July 2009 opening an autonomous tariff quota for imports of high-quality beef; Commission Regulation No 620/2009 of 13 July 2009 providing for the administration of an import tariff quota for high-quality beef; Regulation No 464/2012 of the European Parliament and of the Council of 22 May 2012 amending Council Regulation No 617/2009; and Commission implementing Regulation No 481/2012 of 7 June 2012 laying down rules for the management of a tariff quota for high-quality beef.

<sup>52</sup> For example, Art. 7.49 of the recent EU – Korea Free Trade Agreement states that the parties will "maintain a dialogue" on certain issues.



### 3.2. GMOs

While in the EU there is a specific legal framework to regulate GMOs, whether for food and feed uses or for cultivation, the applicable US legal and regulatory framework is comparatively basic and limited to non-binding policy statements on the application of existing product-related laws to GMOs.

In the EU, the precautionary principle plays an important role in risk management, and placing GMOs on the market is thus subject to an authorisation procedure that must comply with specific requirements, such as the submission by the applicant of an extensive risk assessment (including an environmental risk assessment); public consultation is also compulsory. By contrast, in the US GMOs are subject to the same rules as conventional products due to an assumption of their “substantial equivalence”, without there being a distinct regulatory regime for GMOs; the FDA has designated GMOs as “generally recognised as safe”, rarely calling for prior approval and largely relying on notification and self-certification by producers. No regime exists that would require monitoring for long-term environmental impacts. Any consultation procedure in the US is of a voluntary nature.

Another difference is the existence of a public register of authorised GMOs in the EU. No comparable GMO register exists in the US, where instead the compiled list of crop varieties no longer subject to any form of regulatory oversight is not readily accessible to the public.

In addition, while labelling of GMOs and products thereof for food use is mandatory under EU legislation (if the proportion of GMOs is higher than 0.9%), it is currently only voluntary under US federal law, although there are early initiatives at the state level to introduce mandatory labelling for improved consumer information.

### 3.3. Regulation of toxic substances

Unlike the Toxic Substances Control Act (TSCA) in the US, the EU’s REACH provides for the registration of all chemicals on the market, establishing several registration deadlines and distinguishing between phase-in substances (i.e. those which existed on the market before REACH came into force) and non phase-in substances (i.e. new chemicals). Conversely, the US’s pre-manufacture notification (PMN) procedure, as established under the TSCA, applies only to chemicals which first came on the market or which were produced for a different use after the Act was passed in 1976. Chemicals which were already on the market were not automatically subject to any requirements under the Act.

Moreover, REACH is much more stringent than TSCA as to the data to be submitted: the technical information that must accompany the registration dossier is very comprehensive, with information required notably on the properties of the chemicals, uses, classification and guidance on safe use, whereas the majority of PMN filings under TSCA only require the submission of pre-existing data on a substance’s qualities and do not ultimately contain any health or safety data whatsoever.

Consequently, where the European Chemicals Agency (ECHA) is able to gather comprehensive safety data on all chemicals through the requirements imposed on registrants in the EU, in the US the Environmental Protection Agency (EPA) has no such comprehensive information, instead relying upon models created from information known about similar substances. Another important difference is that TSCA imposes only a small number of specific restrictions (conditions on use or ban) on chemicals, instead giving the EPA the authority to impose such restrictions if it determines that a chemical substance poses an unreasonable risk to human health or the environment. However, courts have interpreted EPA’s power to do so to be quite restricted. On the other hand, under REACH, restrictions are clearly stated in the legislation, and apply as such.

Finally, under TSCA a large amount of information on chemicals may be kept confidential. Other laws and regulations within the US ensure that products meet international labelling standards (U.S. Environmental Protection Agency, 2013), however the data available to the public from the EPA is significantly more limited than what the EU makes available via the REACH Classification and Labelling Inventory.

In a more general sense, the US reliance upon common law has the consequence of making judicial decisions extremely influential in how laws are interpreted and enforced, sometimes altering what many saw as the objective of the legislation in the first place (Renn and Elliott, 2011). By contrast, within the EU the power of the judiciary to modify rather precise law through judicial interpretation is more limited.

It is possible that TTIP will be an impetus for American legislators to strengthen their chemical regulation regime, to align it better with REACH, as this issue has been pushed within Congress since 2005. There is currently legislation on the table which would strengthen data gathering on extant chemicals and create better alignment with REACH, but it is unclear if it will make it through the Congress, as environmental and consumer groups are criticising it for being too weak (Heyen, 2013).

### **3.4. Chlorinated poultry**

Both the EU and the US possess a comprehensive regulatory framework on substances allowed in the production and processing of poultry. In the EU, this framework forms part of the 'Hygiene Package' of 2004 comprising three regulations; in the US, the general framework is set out in two federal statutes, and details are contained in directives and regulations promulgated by the implementing agencies, the Food and Drug Administration (FDA) and the Food Safety and Inspection Service (FSIS). In essence, both jurisdictions subject the use of substances or ingredients to treat poultry to an approval regime, with a specified approval process. A major difference lies in how this regime has been implemented, or, in other words, which substances each jurisdiction currently allows for the treatment of poultry.

Whereas chlorine dioxide, acidified sodium chlorite, trisodium phosphate, and peroxyacids have been approved as pathogen reduction treatments (PRTs) to decontaminate poultry in the US, the EU currently only allows use of water to remove contaminants. This difference reflects conflicting assessments of the safety and suitability of such PRTs for use in poultry products. Given the approval procedure in place in the US, and because scientific and technical bodies in Europe and at the international level have suggested that the use of PRTs is likely safe (European Food Safety Authority (EFSA), 2012)<sup>53</sup> (although some reviews highlighted a lack of data, especially on the effect of disposal for the environment (European Food Safety Authority (EFSA), 2008)), it may be inaccurate to simply ascribe the regulatory differences to a general tendency towards less regulation or greater industry-friendliness in the US, as is the case with GMOs. The rejection of the Commission proposal to authorise PRTs was expressly based on the desire not to undermine EU food safety standards, consumer confidence and the competitiveness of the EU's poultry industry (because of important investments to comply with strict EU standards) (USDA Foreign Agricultural Service, 2008).

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<sup>53</sup> See also Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme Codex Committee on Food Hygiene Guideline for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat, 2012, CAC/GL 78-2011, <http://www.codexalimentarius.org/>

### 3.5. Aviation

Greenhouse gas emissions from the aviation sector are among the fastest growing emissions worldwide, and are expected to continue on a trajectory of rapid growth (Lee, 2010). With the Kyoto Protocol providing in its Article 2.2 that "Parties included in Annex I shall pursue limitation or reduction of emissions of greenhouse gases ... from aviation ... working through the International Civil Aviation Organisation", efforts to arrive at an international solution to address emissions from aviation have largely focused on ICAO, a specialised agency of the United Nations. So far, however, the track record of ICAO has left observers largely underwhelmed (European Federation for Transport and Environment, 2010), prompting the EU to conclude that international efforts were "insufficiently stringent"<sup>54</sup> and causing it to extend the scope of the EU ETS to both domestic and international flights arriving at or departing from airports within the EU.

In the US, no comparable measures have been adopted, partly due to strong lobbying from airline federations such as the Air Transport Association of America, now Airlines for America. Instead, the US Congress adopted a bill prohibiting US airlines from complying with the requirements under the EU emissions trading scheme (ETS), and indemnifying them from any negative consequences. Intense international pressure has caused the EU to temporarily derogate the inclusion of international flights from their obligations under the EU ETS, and signal readiness for a compromise solution until an international market-based instrument can be adopted under ICAO in 2016, entering into force in 2020. In the meantime, the EU will only cover aviation emissions over its airspace, while emissions over US airspace will be subject to no constraints, under either US or EU law. A multilateral agreement thus becomes all the more important.

### 3.6. Summary

While generalisations should be avoided when comparing regulatory approaches on either side of the Atlantic, the preceding analysis has shown remarkable differences in the depth and stringency of regulation applied to genetically modified organisms, substances to treat poultry, chemicals, and emissions from aviation. Overall, a pattern is apparent wherein the US have chosen to either not acknowledge risks to the environment and human health recognised by the EU, or to address such risks in ways which markedly differ from the approach chosen in Europe, for instance by merely promulgating voluntary guidelines rather than mandatory requirements. In some cases, this has even resulted in explicit efforts to undermine measures taken in the EU, such as the inclusion of international aviation in the EU ETS where the US has adopted legislation actively barring US air carriers from compliance with EU requirements and indemnifying them from liability.

For the case studies assessed in this section, it can therefore be safely affirmed that the regulatory intensity in the EU is higher than in the US, with the private sector facing fewer requirements and enjoying significantly greater flexibility in the US. The reasons for this divergence is difficult to assess and is arguably due in varying degrees to successful lobbying and media campaigns by industry, different consumer preferences, and broader differences in perception of environmental concerns.

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<sup>54</sup> European Union, Written Statement of Reservation by Belgium on Behalf of the European Union (EU), its 27 Member States, and the 17 other States Members of the European Civil Aviation Conference (ECAC) on Resolution A37-17/2: Consolidated Statement of Continuing ICAO Policies and Practices Related to Environmental Protection – Climate Change, 2010.

However, it should also be noted that scholarly texts comparing US and EU approaches to risk regulation and environmental standards in a huge number of issues areas do not identify a consistent pattern of either the US or EU following a more precautionary approach to environment or health protection (Wiener et al., 2011). In some areas, the US has a more precautions stance, in others the EU does. Other accounts find that historically the US was more precautionous in earlier decades, but since about 1980s the EU has the more precautionary stance (Vogel, 2003). How these differences may affect, or be affected by, the TTIP negotiations is difficult to predict, but it is clear that interests and starting premises diverge widely on either side of the Atlantic.

## 4. RECOMMENDATIONS

The following conclusions and recommendations are addressed at the European Parliament, cognizant of the limited role the European Parliament has in EU trade negotiations. The most powerful tool available to the European Parliament is certainly the threat of not giving its consent to a negotiated agreement, a route it has occasionally chosen in the past (e.g. in the case of the Anti-Counterfeiting Trade Agreement - ACTA). Beyond this, however, the European Parliament could also play a role in creating public attention around the negotiations and its impact, helping to stimulate political debate about a potential agreement.

Generally, the impact of a future TTIP on the EU environmental and food safety *acquis* as well as its larger environmental impact will strongly depend on the precise provisions of the agreement. We hence recommend that the European Parliament pay particular attention to the following general issues in order to ensure that a future TTIP allows both parties to maintain the level of (environmental) protection they deem appropriate, as set forth in the negotiating guidelines:

- When the Sustainable Impact Assessment on TTIP has been conducted, the European Parliament should carefully and critically re-assess this impact assessment, either through its own impact assessment unit or through the use of external experts.
- Any proposed clause should be thoroughly reviewed and assessed with a view to its potential impact on the EU regulatory *acquis* and the EU's freedom to pursue non-economic policy goals in the future. This may require careful legal and political analysis of seemingly technical language, e.g. on investment protection or chemical regulation.
- The aim of any proposed clause should be assessed with a view to its necessity and whether the purported aim could be reached equally well through other means. For example, while provisions on investor-state dispute resolution may be required in agreements with countries where no efficient, rule-of-law judicial system exists, this is more doubtful in two highly evolved legal systems like the EU and US.
- To avoid doubt and prevent expansive interpretation by arbitration tribunals, critical terms used in the agreement (e.g. expropriation) should be clearly defined; thorough attention should be given to the formulation of (exception) norms allowing governments to take action for non-economic goals (e.g. environmental protection or food safety). Past experience with the WTO's exception norms may provide useful guidance in this regard.

More specifically and with regard to the policy areas discussed more in-depth in this study, we recommend the following:

- In light of the highly differing EU and US regulations applicable to GMOs, any TTIP provisions which could apply to GMOs should be carefully reviewed, in order not to inadvertently undermine the stricter EU standards for the authorisation of GMOs (e.g., risk assessment), as well as transparency of GMO-related information (notably public consultation, register and labelling).

- In the area of regulation of toxic substances, the EU REACH Regulation is more comprehensive (in terms of the chemicals to which it applies) and more stringent (notably in terms of the data to be submitted) than its US counterpart TSCA. It would be necessary to ensure that no TTIP provision unintentionally undermines REACH, in particular regarding the requirements for the placing on the market of chemicals, as well as its provisions on transparency and public access to information. TTIP could actually be an impetus for US legislators to strengthen their chemical regulation regime and align it better with REACH.
- Of the environmental policy areas we have investigated in this study, the area of chlorinated poultry appears likely to be debated during TTIP negotiations. This is particularly likely as the EU ban on US poultry treated with PRTs does not appear to be primarily based on human health or environmental concerns, but rather on the will to uphold EU food safety standards, to not undermine consumer confidence and the competitiveness of the EU's poultry industry. There is nonetheless a lack of data on the effect of disposal for the environment. It may be advisable to assess the justification for the import ban and ensure it is entirely based on legitimate concerns, e.g. an application of the precautionary principle in the area of health or environmental protection, rather than an interest to safeguard the competitiveness of the EU's poultry industry.
- On the issue of aviation, progress in the multilateral negotiations and a willingness of the EU to compromise by amending its legislation has arguably reduced the potential for conflict between the US and EU in this area. Overall, this issue is probably less likely to feature directly in the TTIP negotiations than the preceding environmental issues. Nonetheless, progress in the multilateral negotiations under ICAO should be carefully monitored to assess whether this disruptive issue threatens to once again strain transatlantic relations and, with it, affect perceptions on the role of environmental concerns in EU-US trade.
- Concerning investor-state dispute resolution (ISDR), there are different ways for avoiding a potential negative impact of such provisions on the EU's right to regulate: For example, ISDR provisions could be avoided altogether, or at least the exhaustion of domestic remedies could be made a pre-condition for using ISDR. Alternatively, ISDR provisions could be included that remedy some of the shortcomings of existing rules and systems, e.g. in the area of transparency or impartiality of arbitrators. If ISRD provisions are included, the substantive obligations of TTIP will have to be reviewed even more carefully with a view to their potential impact on the EU's right to regulate.

## ANNEX 1: BACKGROUND INFORMATION TO IDENTIFY RELEVANT AREAS

### History of WTO dispute settlement

From the history of WTO dispute settlement, six disputes over either EU or US environmental/food safety regulations could be identified where the two parties were on opposing sides and which were not resolved amicably.<sup>55</sup> In an early case, Venezuela had challenged before the WTO dispute settlement body a US measure on regulations on the composition and emissions effects of gasoline used by vehicles taken in order to improve air quality and the EU joined as third party, opposing certain aspects of the US measure.<sup>56</sup> The US measure was found to violate WTO law, and the US subsequently changed it. The next dispute was initiated by the US and Canada in 1996 over an EU ban on beef treated with certain **growth hormones**, which affected US (and Canadian) exporters.<sup>57</sup> The EU was found to be in violation of WTO law, and as the EU failed to implement the WTO dispute settlement ruling within the defined timeframe, the US was authorized to take countermeasures; it did so by imposing a 100% duty on certain EU products amounting to an overall volume of 116.8 million US dollars per year, considered to be the equivalent of the damage suffered by the US from the EU ban on hormone-treated beef. The EU initiated another settlement procedure before the WTO in 2004, claiming that the continued sanctions by the US themselves violate WTO law, given that the EU had in the meantime brought its measures into conformity with WTO law.<sup>58</sup> The dispute settlement bodies ruled that the EU measures in place, Directive 2003/74/EC, continued to violate WTO law and the US was hence not in violation of WTO law through imposing sanctions on EU imports. However, the Appellate Body for procedural reasons could not resolve all legal issues and thus recommended that the parties initiate yet another WTO procedure. In May 2009, the EU and the US signed a Memorandum of Understanding (MoU) "regarding the importation of beef from animals not treated with certain growth-promoting hormones and increased duties applied by the United States to certain products of the European Communities", which they notified the WTO of in September of that same year. Based on this MoU, which established a process in several steps, the EU increased its duty-free import quotas for hormone-free beef (High Quality Beef) through successive Regulations,<sup>59</sup> and, in exchange, the US gradually lifted its sanctions. In the Shrimp - Turtle dispute over a US **import ban on shrimp** caught with certain measures endangering sea turtles the EU joined as a third party, partially supporting the US position, partially disagreeing with it.<sup>60</sup> The US ban was first held to be incompatible with WTO law, but after the US had made certain additional efforts it was later considered to be in line with WTO law.

<sup>55</sup> A list of disputes by countries can be found at

[http://www.wto.org/english/tratop\\_e/dispu\\_e/dispu\\_by\\_country\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/dispu_by_country_e.htm)

<sup>56</sup> United States — Standards for Reformulated and Conventional Gasoline, WT/DS2,

[http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds2\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds2_e.htm)

<sup>57</sup> European Communities — Measures Concerning Meat and Meat Products (Hormones), WT/DS26,48,

[http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds26\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds26_e.htm)

<sup>58</sup> United States — Continued Suspension of Obligations in the EC — Hormones Dispute, WT/DS306,

[http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds320\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds320_e.htm)

<sup>59</sup> Council Regulation No 617/2009 of 13 July 2009 opening an autonomous tariff quota for imports of high-quality beef; Commission Regulation No 620/2009 of 13 July 2009 providing for the administration of an import tariff quota for high-quality beef; Regulation No 464/2012 of the European Parliament and of the Council of 22 May 2012 amending Council Regulation No 617/2009; and Commission implementing Regulation No 481/2012 of 7 June 2012 laying down rules for the management of a tariff quota for high-quality beef.

<sup>60</sup> United States — Import Prohibition of Certain Shrimp and Shrimp Products, WT/DS58, [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds58\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds58_e.htm)

The next relevant dispute was a complaint filed by the US and others over the EU's failure to give approval for the marketing of certain **genetically modified organisms** (GMOs) and certain related measures by EU Member States.<sup>61</sup> The EU lost the case in front of the Panel on procedural grounds. It did not appeal the Panel's finding and adopted a new GMO regime. Thus, the US and the other complainants took no counter-measures; so far there has been no other complaint. The next complaint (over an EU environmental measure) was initiated in 2007 by Canada, but the US joined as a third party. Canada complained over certain measures taken by Belgium and the Netherlands regarding the importation, transportation, manufacturing, marketing and sale of **seal products**.<sup>62</sup> A Panel was established in 2011, but has not taken any decision yet. Finally, the US has also raised issues over the EU treatment of **poultry products** before the WTO dispute settlement;<sup>63</sup> the EU prohibits the import of poultry treated with any substance other than water unless that substance has been approved by the EC. This has the effect of inhibiting imports of nearly all US chicken, as these usually get treated with chemicals not approved by the EC.<sup>64</sup> A panel has been established, but not yet taken any decision.

A 2011 ECJ case initiated by US companies concerned the inclusion of aviation in the **EU's emissions trading scheme** (ETS).<sup>65</sup> The US companies had brought a suit before a British court, attacking British measures implementing the EU ETS; the UK court had then referred the matter to the ECJ. The ECJ upheld the EU measures, but did not investigate WTO law specifically.

## EU and US trade reviews conducted at the WTO

One interesting source of information about (potential) trade conflicts are the periodic trade policy reviews undertaken at the WTO. The reviews are conducted every two years for the biggest trading nations (including the US and the EU) and every four or six years for other WTO Members, depending on their share in world trade. Reviews proceed on the basis of a policy statement by the WTO Member under review and a report prepared by the WTO Secretariat. Other WTO Members have the opportunity to ask questions or offer comments on the respective Member's trade policies, often indicating areas of concern to them.<sup>66</sup> Minutes of the trade review meetings are public, and thus often a good "early warning system" for future trade conflicts.

Thus, we have analysed the latest trade reviews for the US and EU respectively.<sup>67</sup> During the December 2012 US trade review, the EU raised issues over US import restrictions for certain **EU beef products** on grounds of BSE risk.

<sup>61</sup> European Communities — Measures Affecting the Approval and Marketing of Biotech Products, WT/DS291, [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds291\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm)

<sup>62</sup> European Communities — Certain Measures Prohibiting the Importation and Marketing of Seal Products, WT/DS369, [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds369\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds369_e.htm)

<sup>63</sup> European Communities — Certain Measures Affecting Poultry Meat and Poultry Meat Products from the United States, WT/DS389, [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds389\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds389_e.htm)

<sup>64</sup> Curiously, in an earlier dispute, which was, however, not pursued any further, the EU had also complained about the US treatment of poultry imports from the EU, see: [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds100\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds100_e.htm)

<sup>65</sup> ECJ Judgment of 11 December 2011, Air Transport Association of America et al. v. Secretary of State for Energy and Climate Change, C-366/10.

<sup>66</sup> For more information see WTO, Overseeing national trade policies: the TPRM, [http://www.wto.org/english/tratop\\_e/tpr\\_e/tp\\_int\\_e.htm](http://www.wto.org/english/tratop_e/tpr_e/tp_int_e.htm)

<sup>67</sup> The trade policy of large WTO Members, such as the US and EU, is reviewed every two years. The related documents are available at [http://www.wto.org/english/tratop\\_e/tpr\\_e/tpr\\_e.htm](http://www.wto.org/english/tratop_e/tpr_e/tpr_e.htm)



The EU also voiced concerns over the establishment of new US requirements for agricultural products being put on the market, which the EU feared could create unnecessary additional delays and costs for imported products, especially by imposing testing on all consignments.<sup>68</sup> In the context of the 2011 EU trade policy review, the US criticised EU import restrictions on food and animal feed products that the US claimed had been safely used within the US for decades; the US specifically named EU biotech rules and regulations on certain pathogen reduction treatments. In the area of technical regulations, the US expressed concerns over the EU chemicals regulation **REACH**, among others; it also complained about EU **fisheries' subsidies**.<sup>69</sup>

## Position statements regarding the potential impacts of TTIP

There have been a large number of publications and position statements regarding the potential impacts of TTIP made by a diverse assortment of well-regarded organisations on both sides of the Atlantic. Of these, we have reviewed those dealing specifically with environmental matters. In Europe the most vocal groups have been Greenpeace, Friends of the Earth Europe, and the Forum Umwelt und Entwicklung<sup>70</sup> along with its coalition partners (including NABU<sup>71</sup> and others); in the United States, the Sierra Club<sup>72</sup> has led the way, along with Friends of the Earth US and Oceana.<sup>73</sup> Nearly all of the groups are concerned that European rules regarding food safety, such as the chlorine washing of poultry and the sales of hormone-injected meats, and regulations on GMOs will be adversely affected, as they may be seen by US negotiators as non-tariff barriers to trade (Steffens, 2013; Greenpeace, 2013; Cingotti, 2013; Forum Umwelt und Entwicklung, 2013; Solomon, 2013; Friends of the Earth U.S., 2013). Additionally, American organisations have highlighted TTIP's potential threat to more stringent European chemical safety regulations (REACH) (Solomon, 2013; Friends of the Earth U.S., 2013), fisheries management (Palmer, 2013), and the possibility that it could be used to prevent national, regional, and/or municipal governments from initiating climate-protective programs and policies (Solomon, 2013; Friends of the Earth U.S., 2013). In general, there is a fear among these NGOs that TTIP will undermine European values and legal principles such as the precautionary and the polluter-pays principles, and will in effect lead to a downward harmonisation of US and EU environmental and food safety standards and regulations, leaving consumers on both sides with fewer protections (Steffens, 2013; Greenpeace, 2013; Cingotti, 2013; Solomon, 2013; Friends of the Earth U.S., 2013). Simultaneous to this stripping of protections from consumers, a number of NGOs and consumer groups foresee an expansion of the rights and privileges afforded large corporations, as the investment portion of TTIP is predicted to include the right of foreign corporations to directly sue governments who enact policies which may adversely affect that corporation's predicted future profits (Cingotti, 2013; Solomon, 2013; Friends of the Earth U.S., 2013; Forum Umwelt und Entwicklung, 2013).

<sup>68</sup> Trade policy review, United States, Record of the Meeting, Trade Policy Review Body 18 and 20 December 2012, WT/TPR/M/275, paras. 195ff.

<sup>69</sup> Trade policy review, European Union, Record of the Meeting, Trade Policy Review Body, 6 and 8 July 2011, WT/TPR/M/248, paras. 163ff.

<sup>70</sup> Forum Umwelt und Entwicklung (English: "Forum Environment and Development") is a German NGO formed in 1992, after the UN Earth Summit (formally the "United Nations Conference on Environment and Development"), and it aims to coordinate the activities of German NGOs within the international political processes surrounding sustainable development ([www.forumue.de](http://www.forumue.de)).

<sup>71</sup> The Naturschutzbund Deutschland (English: "Nature and Biodiversity Conservation Union"), or "NABU," was founded in 1899 and is one of Germany's largest and oldest environmental groups ([www.nabu.de](http://www.nabu.de)).

<sup>72</sup> The Sierra Club, founded in 1892 by John Muir, is the oldest and largest environmental NGO in the United States ([www.sierraclub.org](http://www.sierraclub.org)).

<sup>73</sup> Oceana, founded in 2001, is an international NGO dedicated to protecting the globe's oceans against pollution and over-fishing ([www.oceana.org](http://www.oceana.org)).

Broadly speaking, from the point of view of environmentally-focused NGOs in Europe and the United States, TTIP is seen as a tool to reduce the protections given to consumers and the environment and to increase the power, influence, and profits of large corporations.

Quite a different impetus can be seen from the positions of US and EU companies who basically support TTIP. Often, these positions do not deal specifically with individual policy areas, but call more broadly for protection of investment and harmonisation of standards. For example, in its position paper the US oil company Chevron seeks to strengthen protections for its investments in the energy sector and expresses that it would welcome, among other things, competitive neutrality for private and state-owned entities, greater protections against discriminatory and unfair treatment, investor-state dispute settlement, and provisions on transparency and involvement in development of legislation and responsible business conduct (Chevron Corporation, 2013). The US Chamber of Commerce also supports higher standards of investment protections, such as those in the US 2012 model BIT (US Chamber of Commerce, 2013). It also calls for a chapter on health protection, i.e. sanitary and phytosanitary measures, which “should reinforce the importance of science- and risk-based regulations and decision-making, including using science-based international standards and scientifically accepted methods that strengthen and elaborate requirements related to risk assessment and risk analysis” (US Chamber of Commerce, 2013). On the EU side, European business organisations are strongly in favour of TTIP. A wide coalition of them launched a Business Alliance to support and assist the governments during the negotiations to signal their strong approval of TTIP and their hope that the agreement will be ambitious and comprehensive and lead to greater growth and new jobs.<sup>74</sup> A more detailed position has been published, for example, by the German industry association BDI. It suggests that the negotiations should remove existing barriers to investments and services. Moreover, they advocate achieving regulatory coherence, which should build on the high levels of environmental, health, consumer etc. protection standards that already exist in the EU and the US. At the same time, the BDI denounces what it considers strict US import provisions for processed animal food and meat products as trade barriers for EU producers and claim that they should be eased. Finally, the BDI also calls for the negotiation of ambitious global rules concerning the access to raw materials and energy, competition rules and trade facilitation (BDI, 2013).

## Literature review

Concerning the literature review, there are a limited number of scholarly texts comparing US and EU approaches to risk regulation and environmental standards. Wiener et al. (Wiener et al., 2011) compare EU and US regulations on a huge number of issues areas, including GMOs, treatment of beef, tobacco, automobile emissions, nuclear power, and chemicals and identify transatlantic differences in most areas. However, they do not identify a consistent pattern of either the US or EU following a more precautionary approach to environment or health protection. In some areas, the US has a more precautions stance, in others the EU does. Other accounts find that historically the US was more precautionous in earlier decades, but since about 1980s the EU has the more precautionary stance (Vogel, 2003). In addition, there are also a number of texts comparing the US and EU approaches in specific areas, including chemical regulation ((US Government Accountability Office, 2007), GMOs (Pollack and Shaffer, 2001), etc. However, this literature, while providing insights into diverging regulatory approaches, does not allow any straightforward conclusions on possible areas of relevance for TTIP.

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<sup>74</sup> Business organisations announce alliance for a Transatlantic Trade and Investment Partnership (TTIP), 16 May 2013, available at: <http://www.businesseurope.eu/content/default.asp?PageID=609>

## ANNEX 2: DESCRIPTION OF THE EU AND US LEGISLATION IN THE IDENTIFIED RELEVANT ISSUES AREAS

In the following we summarise the EU and US regulation on each of the issues areas identified in Chapter 2. Within the scope of this study, it is not possible to conduct a full-fledged legal analysis of the wording of the norms in both legal orders; rather, the analysis is based on secondary information (e.g. description of relevant legal norms by the competent ministries, etc.).

### GMOs

#### EU

The legal framework regulating GMOs in the EU is governed notably by Directive 2001/18/EC on the deliberate release of GMOs into the environment, Regulation No 1829/2003 on genetically modified food and feed, and Regulation No 1830/2003 on GMO traceability, labelling, and derived food and feed, as amended.<sup>75</sup>

The placing on the market of GMOs in the EU is subject to an authorisation procedure that must comply with the requirements set in Directive 2001/18/EC in accordance with the precautionary principle (which is recognised as an overarching principle that must be taken into account when implementing the Directive<sup>76</sup>), and specific requirements laid down in Regulation 1829/2003. The application dossier notably includes experimental data and an extensive risk assessment. Public consultation is compulsory. Authorisations are valid throughout the EU for ten years and are renewable. Depending on the type of application (for cultivation vs. for food and feed uses), the authorisation process is carried out at the Member State level or at the EU level, although in this latter case the application must still be sent to the national competent authority of a Member State.

If the application covers only cultivation (or the introduction of GMOs for experimental purposes), the procedure established under Directive 2001/18/EC will apply: the applicant must apply to the competent authority of the EU Member State where the GMO is to be initially marketed. The national authority will then prepare an assessment report. If another Member State objects to the findings of this report, the application is referred to European Food Safety Authority (EFSA).

When an authorisation is sought for food and feed uses and for cultivation, the industrial operator submits a single application. Under Regulation No 1829/2003 on GM food and feed, the authorisation process is centralised, i.e. it is carried out by the EU: the national competent authority receiving the application makes it available to the EFSA, which is responsible for the risk assessment. If the application also covers cultivation, EFSA delegates the environmental risk assessment to an EU Member State, which will draft a report and send it back to EFSA to be taken into account in the single authorisation procedure.

<sup>75</sup> Other pieces of legislation include Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species, Directive 2002/55/EC on the marketing of vegetable seed, Regulation (EC) No 1946/2003 on transboundary movements of GMOs, Directive 2009/41/EC on the contained use of GMOs, Commission Regulation (EU) No 619/2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of GM material.

<sup>76</sup> The precautionary principle is mentioned throughout the Directive. In particular, Art.4(1) provides, as a general obligation: "Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs." The Directive provides also "in accordance with the precautionary principle" for a set of general principles that must be followed when performing the environmental risk assessment (see Annex II).

Based on EFSA's findings, the Commission draws up a draft decision (to grant or refuse authorisation), which is then submitted to the Standing Committee on the Food Chain and Animal Health, composed of representatives of the Member States and chaired by a representative of the Commission. If the Committee accepts the proposal, it is then adopted by the Commission. If it is not accepted, the Commission must submit the proposal to the Council of Agricultural Ministers for assessment, and inform the European Parliament. The Council acts (and where appropriate in view of the position of the European Parliament) by qualified majority. If the Council members do not reach an agreement within the established time period (i.e. does not adopt the proposed implementing act or indicate its opposition to the proposal), the Commission adopts its proposal.

When an authorisation is issued, Member States may, as a result of new or additional information made available since the authorisation was granted, invoke the 'Safeguard clause' (Art. 23 of Directive 2001/18/EC) to temporarily restrict or prohibit the use and/or sale of the GMO as such or as a component of a product on its territory. Such a decision must be justified by a risk to human health or the environment. The Commission must then make a decision on the matter (overturn the original authorisation or request the Member State to withdraw its provisional restriction), subject to the regulatory procedure described in the previous paragraph (draft decision submitted to the Standing Committee with the possible intervention of the Council).

In 2010, the Commission proposed new rules for the authorisation of GMOs, regarding the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory (on grounds other than the risk assessment, provided they are in conformity with the Treaty);<sup>77</sup> the Commission's proposal underwent the legislative process. The EP supported the possibility for Member States to adopt national bans, on a wider number of grounds than the Commission had proposed.<sup>78</sup> However, no agreement was reached on the compromise proposal presented to the Council.<sup>79</sup> The Commission also adopted non-binding guidelines<sup>80</sup> for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops (through the use of buffer zones and isolation distances, and the possibility to designate GMO-free zones). In addition, in case of modification of, or unintended change to, the deliberate release of GMOs with consequences with regard to human health and the environment, or when new information becomes available on these risks, the authorisation may be modified, suspended or terminated (Art.8(2) of Directive 2001/18/EC).

Regulation No 1829/2003 also requires the labelling of GMOs and products thereof for food use when they contain, consist of, or are produced from GMOs in a proportion higher than 0.9% of the food ingredients considered individually or food consisting of a single ingredient (Art.12(2)). The same applies for feed containing material where the proportion of GMOs is higher than 0.9% of the feed and of each feed of which it is composed (Art.24(2)).

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<sup>77</sup> See notably the Commission's proposal for a Regulation amending Directive 2001/18/EC (COM(2010) 375 final). [http://ec.europa.eu/food/plant/gmo/legislation/docs/proposal\\_en.pdf](http://ec.europa.eu/food/plant/gmo/legislation/docs/proposal_en.pdf)

<sup>78</sup> European Parliament, GMOs: Parliament backs national right to cultivation bans, Press release of 5 July 2011, available at: <http://www.europarl.europa.eu/sides/getDoc.do?type=IM-PRESS&reference=20110705IPR23305&secondRef=0&language=EN>

<sup>79</sup> See [http://ec.europa.eu/prelex/detail\\_dossier\\_real.cfm?CL=en&DosId=199527#411959](http://ec.europa.eu/prelex/detail_dossier_real.cfm?CL=en&DosId=199527#411959); and the Council's Press Release of 9 March 2012 available at: [http://ec.europa.eu/prelex/detail\\_dossier\\_real.cfm?CL=en&DosId=199527#411959](http://ec.europa.eu/prelex/detail_dossier_real.cfm?CL=en&DosId=199527#411959)

<sup>80</sup> Commission Recommendation C(2010) 4822 final: [http://ec.europa.eu/food/plant/gmo/legislation/docs/new\\_recommendation\\_en.pdf](http://ec.europa.eu/food/plant/gmo/legislation/docs/new_recommendation_en.pdf)

If the proportion is less than 0.9%, labelling is not required, provided that the presence of the GMO is adventitious or technically unavoidable. Regulation (EC) No 1831/2003 sets specific requirements for the traceability of GMOs at each stage of production and placing on the market, with monitoring of labelling and of the potential effects on human health or the environment.

In implementation of Directive 2001/18/EC, the EU has established a register of authorised GMOs.<sup>81</sup>

## US

Compared to the EU, the US has only adopted a very basic legal and regulatory framework to address potential risks arising from the production and use of GMOs. A crucial difference arises from the fact that GMOs are not subject to a distinct regulatory regime, but essentially fall within the purview of the rules applicable to conventional products. Although subject to a controversial debate, labelling for GMOs is not mandated under federal law. Still, the particular features and novel uses of GMOs have necessitated adoption of sub-statutory regulations and guidance on the application of existing law. Public pressure from consumer and environmental groups may result in the introduction of more stringent rules specifically targeting GMOs at the state or federal level.

The rapid growth of the US biotechnology sector in the early 1980s prompted the White House Office of Science and Technology Policy to adopt a Coordinated Framework for Regulation of Biotechnology in 1986, establishing a "comprehensive federal regulatory policy for ... biotechnology research and products."<sup>82</sup> Developed during a period in which political decision makers favoured deregulation rather than new environmental restrictions, this regime reflected a general assumption, which does not appear as having been based on a thorough risk assessment, that biotechnology itself posed no unique risks and did not hence require an additional regulatory regime; instead, only the products of biotechnology – rather than the processes themselves – should be subject to regulation, based on the composition and intended use of such products. Consequently, the Coordinated Framework declared existing statutory and regulatory provisions on the health, safety, efficacy, and environmental impacts of conventional commercial products sufficient to also regulate products obtained through biotechnology.<sup>83</sup>

Thus, no single statute or federal agency governs the regulation of GMOs. Instead, more than ten different statutes and numerous agency regulations and guidelines cover commercial products such as food, animal feed, human and animal drugs and biological medical products, pesticides, plant pests, and toxic substances, irrespective of the production process or whether these involve the use of biotechnology or GMOs.<sup>84</sup>

<sup>81</sup> Available at [http://ec.europa.eu/food/dyna/gm\\_register/index\\_en.cfm](http://ec.europa.eu/food/dyna/gm_register/index_en.cfm)

<sup>82</sup> Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

<sup>83</sup> On the Coordinated Framework and the history of biotechnology regulation in the United States more generally, see (Marden, 2003; Mandel, 2006).

<sup>84</sup> Major statutes conferring the regulatory or review authority in the area of genetically modified products include: the Federal Insecticide, Fungicide and Rodenticide Act; the Toxic Substances Control Act; the Food, Drug and Cosmetics Act; the Plant Protection Act; the Virus Serum Toxin Act; the Public Health Service Act; the Dietary Supplement Health and Education Act; the Meat Inspection Act; the Poultry Products Inspection Act; the Egg Products Inspection Act; and the National Environmental Protection Act. For a more detailed overview, see (Pew Initiative, 2001).

Three federal agencies regulate genetically modified plants and animals in the US, namely the Food and Drug Administration (FDA),<sup>85</sup> which is tasked with ensuring the safety of food and animal feed, the safety and efficacy of human drugs and biologics, and animal drugs; the Environmental Protection Agency (EPA), which is broadly responsible for federal environmental policy, including the regulation of toxic substances and microorganisms, the use of pesticides, and allowable levels of pesticide residues in food; and the United States Department of Agriculture (USDA), which is broadly responsible for federal agricultural policy.<sup>86</sup>

In recent years, advances in biotechnology have made it more difficult to subsume new genetically modified products under existing product categories, prompting adoption of specific regulations and guidance in different areas addressing the application of existing laws to such products, setting out detailed definitions, clarifications, and procedures in the form of narrative text, often in a question-and-answer format.<sup>87</sup> In the case of food and food crops for instance, the FDA adopted a non-binding statement of policy clarifying its interpretation of the Federal Food, Drug, and Cosmetic Act (FFDCA)<sup>88</sup> as it relates to GMOs.<sup>89</sup> Genetically modified food is considered “substantially equivalent” to conventional food and designated as “generally recognized as safe” without prior approval; food producers or manufacturers are held responsible for the safety of their products.<sup>90</sup> Additional guidance published in 2006 sets out recommendations on the food safety evaluation of proteins produced by genetically modified plant varieties, without however specifying any binding requirements.<sup>91</sup>

Developers of genetically modified crop varieties have to file a notice of intent and submit summary data prior to field testing, and will receive an acknowledgment from the USDA within 30 days. Only experimental varieties that pose a particular risk are subject to a permit requirement.<sup>92</sup> If and when a genetically modified crop variety is considered ready for commercial sale, the producer applies for a “determination of non-regulated status”, removing the crop variety from further oversight or testing.

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<sup>85</sup> Four centres have responsibility for biotechnology products within the FDA: the Center for Food Safety and Applied Nutrition; the Center for Veterinary Medicine; the Center for Drug Evaluation and Research, and the Center for Biologics Evaluation and Research.

<sup>86</sup> Within USDA, the Animal and Plant Health Inspection Service (APHIS) has primary responsibility for biotechnology regulation, with additional responsibilities for the Food Safety and Inspection Service (FSIS).

<sup>87</sup> A case in point are crop plants that have been genetically modified to create their own pesticide, constituting a product that simultaneously is a potential plant pest, a food, and a pesticide; in response, the EPA developed new regulations on Plant-Incorporated Protectants. See EPA, Plant Incorporated Protectants, <http://www.epa.gov/opp00001/biopesticides/pips/> for a list of applicable regulations.

<sup>88</sup> 21 U.S.C.

<sup>89</sup> FDA, Statement of Policy – Foods Derived from New Plant Varieties: Guidance to Industry for Foods Derived from New Plant Varieties, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm>

<sup>90</sup> See *ibid.*, Sec. V (B): “Ultimately, it is the responsibility of the producer of a new food to evaluate the safety of the food and assure that the safety requirement of section 402(a)(1) of the act [i.e. the Federal Food, Drug, and Cosmetic Act] is met.” Only when the insertion of a transgene into a food crop results in the expression of foreign proteins that differ significantly in structure, function, or quality from natural plant proteins and are potentially harmful to human health, FDA has the authority under Sec. 401(a)(1) FFDCA to apply more stringent provisions requiring the mandatory pre-market approval of food additives, whether or not they are the products of biotechnology, see Federation of American Scientists, U.S. Regulation of Genetically Modified Crops, <http://www.fas.org/biosecurity/education/dualuse-agriculture/2.-agricultural-biotechnology/us-regulation-of-genetically-engineered-crops.html>

<sup>91</sup> FDA, Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use, 2006, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096156.htm>

<sup>92</sup> Covered varieties are such that are listed on a national registry of noxious weeds, are deemed genetically unstable, contain genes of unknown function, have toxic, infectious, or pharmaceutical properties, contain genetic material from an animal or human pathogen, or are deemed to pose a risk of creating a new plant virus.

A similar approach has been chosen by the EPA for the regulation of pesticides and other protectants genetically incorporated into crop varieties. It also relies largely on data provided by producers and prescribes no mandatory set of laboratory tests or long-term monitoring regimes (Tokar, 2006).

While additional guidance issued in 1997 recommended a voluntary “consultation procedure” by food crop developers to determine “substantial equivalence” before a crop is put on the market, the EPA still relies on the developer to provide the relevant safety and nutritional data.<sup>93</sup> Due to the voluntary nature of this consultation procedure, critics have questioned its ability to provide assurance of the safety of genetically modified crops and the food produced therefrom. A peer-reviewed study published in 2004 criticised that “claims regarding the safety of these crops ... are founded mostly on unpublished studies conducted by the crop developer” (Freese and Schubert, 2004: 299). Likewise, a report by the National Academy of Sciences published in 2002 censured these safety studies’ for lack of scientific rigor and transparency in data, methods, analyses, and interpretations, expressing concern about the absence of long-term environmental monitoring and noting that “any effects that might have occurred could not have been detected. The absence of evidence of an effect is not evidence of absence of an effect” (National Academy of Sciences, 2002: 79). Even the USDA Inspector General has observed that weaknesses in applicable regulations and internal management controls “increase the risk that regulated genetically engineered organisms will inadvertently persist in the environment before they are deemed safe to grow without regulation” and complained that the agency “lacks basic information about the field test sites it approves and is responsible for monitoring, including where and how the crops are being grown, and what becomes of them at the end of the field test” (US Department of Agriculture (USDA) Office of the Inspector General, 2005: 2). Attempts to pass more stringent legislation addressing these shortcomings have so far failed,<sup>94</sup> and the feasibility of assessing the long term effects of GMOs has been questioned, given the difficulty of assembling a viable control group (US Government Accountability Office, 2002: 34).

Concerns about the safety of GMOs in food have also prompted an on-going discussion of labelling obligations for food containing GMOs. At present, the FDA position on labelling is consistent with its policy statement that genetically modified food crops are not materially different from conventional crops, prompting no additional disclosure requirements.<sup>95</sup>

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<sup>93</sup> FDA, Consultation Procedures under FDA's 1992 Statement of Policy: Foods Derived from New Plant Varieties Guidance on Consultation Procedures, Revised October 1997, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096126.htm>. Such data should contain sufficient information for the FDA to understand the approach taken by the producer in identifying and addressing relevant issues, and “would ordinarily include: the name of the bioengineered food and the crop from which it is derived; a description of the various applications or uses of the bioengineered food, including animal feed uses; information concerning the sources, identities, and functions of introduced genetic material; information on the purpose or intended technical effect of the modification, and its expected effect on the composition or characteristic properties of the food or feed; information concerning the identity and function of expression products encoded by the introduced genetic material, including an estimate of the concentration of any expression product in the bioengineered crop or food derived thereof; information regarding any known or suspected allergenicity and toxicity of expression products and the basis for concluding that foods containing the expression products can be safely consumed; information comparing the composition or characteristics of the bioengineered food to that of food derived from the parental variety or other commonly consumed varieties with special emphasis on important nutrients, and toxicants that occur naturally in the food; a discussion of the available information that addresses whether the potential for the bioengineered food to induce an allergic response has been altered by the genetic modification; any other information relevant to the safety and nutritional assessment of the bioengineered food.”

<sup>94</sup> See, e.g., S. 2546, “Genetically Engineered Foods Act”, introduced 17 June 2004, sponsored by Senator Richard Durbin.

<sup>95</sup> See FDA, Statement of Policy – Foods Derived from New Plant Varieties: Guidance to Industry for Foods Derived from New Plant Varieties, note 89, Sec. VI: “the agency does not believe that the method of

Draft guidance to industry on voluntary labelling of genetically modified food issued by the FDA in 2001 affirms that labelling should not be required, as it would express or imply that “food is superior (e.g., safer or of higher quality) because it is not bioengineered” and hence “be misleading.”<sup>96</sup> Still, the FDA acknowledges public interest in related information, suggesting that “some manufacturers may want to respond to this consumer desire” by voluntarily labelling their products. In a landmark case on GMO product labelling, a US District Court finally rejected claims that the FDA had acted in an arbitrary or capricious manner when it determined that a genetically engineered food component was safe; additionally, the Court stated that consumer demand was not a basis for requiring a food label.<sup>97</sup>

Overall, the US policy framework can be understood as the product of an ambivalent institutional mission: in the case of food and food crops, for instance, the FDA has sought simultaneously to ensure food safety and to promote biotechnology in agriculture (Marden, 2003). And yet, while the US regulatory framework on GMOs thus remains very rudimentary at best, growing public concern is already prompting changes at the local and regional level. A 2012 referendum in California that was narrowly defeated, Proposal 37, would have mandated labelling of genetically modified food products. Similar initiatives are underway in several other states, and both Connecticut and Maine have recently passed mandatory labelling laws whose entry into force is conditional on at least four other US states adopting similar laws.<sup>98</sup> While these dynamics at the state-level may yet be stalled by litigation, they can be seen as a manifestation of latent political pressure for more stringent federal regulation of GMOs in the US.

## Regulation of toxic substances

### EU

The EU adopted general legislation on chemicals through Regulation (EC) No 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),<sup>99</sup> which entered into force on 1 June 2007.

The Regulation is applicable to manufacturers or importers of chemical substances as well as the “only representative” who complies with obligations of importers by a mutual agreement.<sup>100</sup> Unless expressly exempted (e.g., medicinal products), all chemicals imported or produced in quantities greater than one tonne per year must be registered through the submission of a registration dossier (one per substance) to the European Chemicals Agency (ECHA).

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development of a new plant variety (including the use of new techniques including recombinant DNA techniques) is normally material information within the meaning of 21 U.S.C. 321(n) and would not usually be required to be disclosed in labelling for the food.”

<sup>96</sup> FDA, Guidance for Industry: Voluntary Labelling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft released for comment January 2001, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm>

<sup>97</sup> *Alliance for Bio-Integrity et al. v. Shalala*, 116 F. Supp. 2d 166 (D.D.C. 2000).

<sup>98</sup> Margaret Badore, “Maine passes second GMO label law in the U.S.,” 13 June 2013,

<http://www.treehugger.com/environmental-policy/maine-passes-second-gmo-label-law-us.html>

<sup>99</sup> There are however legislations specific to certain chemicals, such as fertilisers, biocidal products, plant protection products, medicinal products, etc.

<sup>100</sup> Pursuant to Article 8(1) and (2) of the REACH Regulation, “a natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title. The representative shall also comply with all other obligations of importers under this Regulation.”



Registration dossiers must include a technical dossier containing information on the properties (through evaluation), uses and classification of a substance, as well as guidance on safe use, and, for substances in quantities of 10 tonnes or more, a chemical safety report (CSR) (European Commission, 2007).

The CSR documents the hazards and classification of a substance and assesses whether the substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB); it describes exposure scenarios for these PBT and vPvB substances. Exposure scenarios need to cover all identified uses, i.e. the manufacturers' or importers' own uses, together with uses made known to them by downstream users.

Companies have the possibility to reduce costs by sharing data for the registration dossier. In principle, they *must* jointly submit information on the hazardous properties of the substance and its classification, but *may* (though are not required to) jointly submit the CSR.

Substances are categorised into two groups under REACH: phase-in substances (existing substances already on the market in the EU before REACH came into force) and non phase-in substances (new substances not covered by the definition of phase-in substances). Each group has different REACH registration deadlines. Several registration deadlines have been set up for the different phase-in tonnage ranges (up to 2018) and for certain substances of high concern (carcinogenic, mutagenic or toxic to reproduction – CMR – and substances which are very toxic to aquatic organisms).

Failure by a company to submit a dossier (or to include a certain use in the dossier) means that it is no longer allowed to manufacture or import this substance (or to use it for an unspecified use, in the case of downstream users notably).

Substances of very high concern (SVHC), i.e. CMR categories 1 and 2,<sup>101</sup> PBT, vPvBs, and substances identified (on a case-by-case basis) as causing probable serious effects to human health or the environment (e.g., endocrine disrupters), are subject to authorisation by the Commission.<sup>102</sup> Substances for which an authorisation is required are included in Annex XIV of REACH, which also establishes those uses to be exempted from the authorisation requirement. Authorisation for use does not apply to imported articles containing SVHC, although notification of the presence of these substances is still required. Any company using or making available such a substance will then need to apply for an authorisation for each use of the substance. The application must include an analysis of possible substitutes and include information on relevant research and development activities, if appropriate. If there are alternatives, the authorisation application will have to include a substitution plan. The Commission may amend or withdraw any authorisation on review if suitable substitutes become available.

REACH (Title VIII) imposes certain "restrictions". Restrictions are conditions established for the manufacture, placing on the market or use of certain substances (on their own, in a preparation or in an article) where there is an unacceptable risk to health or the environment, or the prohibition of any of these activities, if necessary. These restrictions are detailed in Annex XVII of REACH, which also specifies if the restriction does not apply to product- and process-oriented research and development, as well as the maximum quantity exempted.

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<sup>101</sup> CMR substances are classified into 3 categories, based on available scientific evidence of the risk they pose to human health.

<sup>102</sup> The authorisation requirement applies to the use(s) of that substance on its own or in a preparation or the incorporation of the substance into an article. See REACH, Art. 56.

REACH also imposes communication requirements on suppliers of a substance or preparation to inform all parties along the supply chain (including downstream users and distributors) of the properties of the substance or preparation to ensure the chemical's safe use. Information is transferred through Safety Data Sheets for all dangerous substances (if present at greater than 0.1% in an article).

REACH includes a requirement for companies to classify and label substances subject to registration and dangerous substances and preparations, and establishes a list of harmonised classifications and the creation of a classification and labelling inventory. Any manufacturer, producer of articles or importer (or group thereof) who places a dangerous substance on the market must notify the ECHA of certain information to be included in the inventory, unless it has been submitted as part of the registration. These provisions were complemented by Regulation No 1272/2008<sup>103</sup>, which incorporates the classification criteria and labelling rules of the UN Global Harmonised System.

## US

The United States regulates the manufacture and sale of chemicals through a number of different laws enforced by multiple separate agencies. The most prominent of these laws is the Toxic Substances Control Act (TSCA)<sup>104</sup> passed in 1976 and administered by the Environmental Protection Agency (EPA). TSCA is concerned primarily with the production of chemicals; in spite of its title, TSCA's regulations do not differentiate between toxic and non-toxic chemicals. TSCA regulates all synthetic and naturally-occurring chemicals (with the exception of those specifically falling under the jurisdiction of another chemical regulation law, such as the Federal Food, Drug, and Cosmetic Act<sup>105</sup> or the Insecticide, Fungicide, and Rodenticide Act<sup>106</sup>). In the wake of a number of chemical-related disasters in the US, the TSCA was passed with the initial intent of shifting the burden of proof of a chemical's safety onto the company producing it (Renn and Elliott, 2011). As such, under Section 4 of TSCA, the EPA may require testing for health and environmental impacts of any chemical substance that is produced in, imported to, or processed in the United States if they find that the chemical may present an "unreasonable risk" (Government Accountability Office, 2005).

Additionally, Section 5 of the Act requires companies to file a "pre-manufacture notification" (PMN) with the EPA in order to receive authorisation either to begin production or importation of a new chemical or to process a pre-existing chemical for what the EPA (through rules it has set and published) determines is a "significant new use" (Government Accountability Office, 2005). The notification is required to include data relating to the chemical's composition, intended production levels and intended uses, as well as any readily available health or safety information. However, companies are not required to create any new health or safety data solely for use in the PMN; consequently, these data are absent from the majority of PMN filings. Instead the EPA generally relies upon its knowledge and understanding of similar substances in order to evaluate the potential dangers of new ones.

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<sup>103</sup> Regulation No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation No 1907/2006.

<sup>104</sup> Text available at <http://www.epw.senate.gov/tsca.pdf>

<sup>105</sup> Available from: <http://www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdact/>

<sup>106</sup> Available from: <http://www.epa.gov/agriculture/lfra.html>

After the submission of a PMN, the EPA has 90 days to evaluate the application and determine if the new product could pose an “unreasonable risk.” If the EPA determines that the proposed chemical or new use will present an “unreasonable risk” to humans or the environment, or that the information submitted is insufficient to make a determination of the risks associated with the substance it can act on its own to limit or ban its production, or it can seek a court injunction to that end (Government Accountability Office, 2005). In the case the EPA concludes that a new product may be harmful, companies may be required to perform testing before receiving permission to produce.

While this has led to streamlined processes for some new, low-risk chemicals, there have also been documented cases of the EPA approving a new product that later proved to pose very serious threats to health and safety (Renn and Elliott, 2011). Furthermore, as this procedure is only used for new products, chemicals on the market prior to when TSCA came into force, which number approximately 55,000 (Schierow, 2013), did not go through this procedure, and in many cases the EPA has had significant difficulty obtaining data on these substances under the authority of Section 4 (Government Accountability Office, 2005).

Section 6 of the act was envisioned by many to give the EPA the power to enforce a precautionary approach to the production of hazardous chemicals, allowing them to regulate or ban the production of anything that poses an “unreasonable risk” to human health or the environment. However, as EPA is allowed to ban chemical production, importation, and processing only when such a ban is the “least burdensome” option before them, courts have interpreted EPA’s power to enact such a ban to be extremely limited (Government Accountability Office, 2005). In most instances, the EPA has been required to provide a factual “record” to submit to courts detailing the dangers of the chemical they wish to regulate. In making their rules, the EPA has not been allowed to rely upon a scientific consensus or even on data pertaining to the chemical in question from a different use or product. Rather, they must have evidence that a particular substance, used in a particular manner or context is in fact harmful. Due to the EPA not usually receiving any data related to health or environmental impact as a part of the PMN process, this section is therefore not generally seen by the EPA as a helpful tool in preventing the production of hazardous substances, especially as the agency has limited financial resources to engage itself in lengthy testing or litigation procedures (Government Accountability Office, 2005; Renn and Elliott, 2011). Particularly problematic in this regard are chemicals that were never required to go through the PMN procedure, as data may be unavailable and there are no longer any pre-emptive actions that the EPA may take.

Even if the EPA does determine that a product on the market is dangerous, it is not always allowed to share this information with the public, or even with other governmental agencies. The EPA is hindered by a requirement in Section 14 of TSCA to keep a large amount of information about chemicals confidential; companies are allowed to in some instances claim testing data as proprietary information, thereby shielding it even from Freedom of Information Act (FOIA) requests by the public or non-federal officials. This requirement is defended by the chemical industry as necessary to prevent the theft of intellectual property, however this stipulation means that the EPA may not even disclose to state and local emergency management authorities which chemicals are produced or stored in their vicinity, nor what types of dangers these substances could pose in the event of an emergency (Government Accountability Office, 2005).

Due to the fact that most chemicals are approved for production without companies providing health and safety data and that many chemicals were on the market before PMNs were mandatory, the EPA does not have comprehensive safety data on most of the chemicals on the market. To rectify this, the EPA has initiated a few voluntary programmes encouraging chemical companies to disclose information about the substances they create. However, these programmes do not include all of even the most common chemicals and do not guarantee that the EPA will receive enough information about a given chemical to determine the level of danger it poses (Government Accountability Office, 2005; Renn and Elliott, 2011).

In 2005, at the request of members of the US Senate, the United States' Government Accountability Office published a report detailing the structure of TSCA and the weaknesses in the government's ability to monitor and regulate the production and sale of potentially dangerous chemicals (Government Accountability Office, 2005). However, efforts to substantially reform the law, including on-going work of the Senate committee tasked with overseeing it, have been extremely controversial and unsuccessful (Trevor's Trek Foundation, 2013; Sciammacco, 2013). A recent proposal written and sponsored by both Republicans and Democrats seeking to increase the EPA's ability to collect data on potentially dangerous chemicals suffered a major setback when its strongest supporter in the Senate passed away only days after the bill's formal introduction (Heyen, 2013).

## Chlorinated poultry

### EU

In 1997, the EU banned the import of poultry carcasses that had been decontaminated using pathogen reduction treatments (PRTs, which include the use of chlorine dioxide, trisodium phosphate, peroxyacids, and acidified sodium chlorite). It also banned the use of PRTs within the EU. The import ban is a result of the failed negotiations on poultry meat between the US and EU (following 1992 European Single Market programme and the GATT Agreement on the Application of SPS Measures), as the Veterinary Equivalency Agreement reached on 30 April 1997 did not cover poultry meat (Xia and Weyerbrock, 1998).<sup>107</sup>

In 2004, the EU adopted the 'Hygiene Package', comprising: (i) Regulation No 852/2004<sup>108</sup> on the hygiene of foodstuffs, which primarily concerns the approval of operators; (ii) Regulation No 853/2004<sup>109</sup> laying down hygiene rules for food of animal origin (unprocessed and processed products of animal origin); and (iii) Regulation No 854/2004<sup>110</sup> laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, which applies in addition to Regulation No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health, and animal welfare rules.<sup>111</sup>

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<sup>107</sup> See also Alisa Pereira, TED Case Studies: EU/US Slaughterhouse Dispute, available at: <http://www1.american.edu/TED/chicken.htm>

<sup>108</sup> No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, OJ L 139, 30.4.2004, p.1.

<sup>109</sup> Regulation No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin, OJ L 139, 30.4.2004, p.55.

<sup>110</sup> Regulation No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, OJ L 139, 30.4.2004, p. 206.

<sup>111</sup> Regulation No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, OJ L 165, 30.4.2004, p.1.

Under Regulation No 853/2004 as amended, establishments handling products of animal origin must be registered and, where necessary, approved by the competent authority in their Member State. Pursuant to this Regulation, poultry must not be treated with any substance other than water to remove surface contamination from products of animal origin, unless use of the substance has been approved by the Commission following a regulatory procedure with scrutiny committee (Art.3 (2)).<sup>112</sup>

A product may be imported into the EU under certain conditions, including compliance with the requirements of the Regulation (Art.6).<sup>113</sup> This entails that imported poultry must comply with Art. 3(2), i.e. be treated only with water, as PRTs have not, to this day, been approved by the Commission.

Furthermore, Council Regulation No 1234/2007 (Single Common Market Organisation - CMO-Regulation), which lays down marketing standards for poultry meat, defines it as "poultry meat suitable for human consumption, which has not undergone any treatment other than cold treatment" (Annex XIV(B)(II)(1)), thus further preventing the import of poultry decontaminated through the use of PRTs.

Pursuant to Articles 11 and 12 of Regulation No 854/2004, the Commission established lists of third countries from which imports of products of animal origin are permitted (Commission Regulation 798/2008), as well as a list of establishments from which products may be imported or dispatched. Currently, only 7 US establishments are listed with regards to poultry.<sup>114</sup> A document certifying, inter alia, that the products satisfy the requirement of Regulations No 852/2004 and 853/2004 or provisions that are equivalent must accompany consignments of products of animal origin that are imported into the Union. The official controls include audits of good hygiene practices and HACCP principles (Hazard Analysis and Critical Control Points), as well as specific controls whose requirements are determined by sector (including fresh meat). Commission Decision 2007/275/EEC lists animals and products subject to veterinary checks at border inspection posts (Annex I), among which are meat and edible offal of poultry, fresh, chilled or frozen.

In 2008, the European Commission submitted a proposal<sup>115</sup> for the import of poultry intended for human consumption which have undergone PRTs, but with special provisions including a labelling requirement.

<sup>112</sup> Pursuant to Articles 3(2) and 12(3) of Regulation No 853/2004, Article 5a of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, applies; this article establishes a regulatory procedure with scrutiny and provides that the Commission must be assisted by a Regulatory Procedure with Scrutiny Committee composed of the representatives of the Member States and chaired by the representative of the Commission. Under this procedure, the proposed measures must also be submitted to the Council and the European Parliament. For details of such procedure, see:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1999D0468:20060723:EN:PDF>

<sup>113</sup> Food imported into the EU must also comply with the general requirements of Regulation No 178/2002 of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

<sup>114</sup> See list at [https://webgate.ec.europa.eu/sanco/traces/output/US/PM\\_US\\_en.pdf](https://webgate.ec.europa.eu/sanco/traces/output/US/PM_US_en.pdf)

<sup>115</sup> Commission submits to SCoFAH proposal setting strict conditions for the antimicrobial treatment of poultry carcasses, Press release, 28 May 2008, [http://europa.eu/rapid/press-release\\_IP-08-819\\_en.htm#PR\\_metaPressRelease\\_bottom](http://europa.eu/rapid/press-release_IP-08-819_en.htm#PR_metaPressRelease_bottom)

The Commission also proposed<sup>116</sup> to amend the EU poultry meat definition to allow marketing of poultry decontaminated using PRTs, but indicated that it would withdraw the proposed amendment if its proposal on the authorisation of PRTs was not adopted. The Standing Committee of the Food Chain and Animal Health almost unanimously voted against the PRT proposal, and the European Parliament adopted a Resolution calling on the Council to reject the Commission's proposal, which it did on 18 December 2008 through Council Decision 2009/121/EC.

## US

The US is the second largest exporter of poultry meat in the world, accounting for about one-third of global poultry trade.<sup>117</sup> Rules on sanitary measures for poultry are set out in a number of federal laws and regulations. Like most other food products, poultry falls within the authority of the United States Department of Agriculture (USDA), which is empowered to adopt more detailed rules and regulations related to poultry and poultry products, operating through the FDA and the Food Safety and Inspection Service (FSIS).

A general framework for poultry products is set out in the Federal Food, Drug, and Cosmetic Act (FFDCA), which provides FDA with the authority to determine the safety, wholesomeness, and accurate labelling of food, and the Poultry Products Inspection Act (PPIA) of 28 August 1957,<sup>118</sup> which affords FSIS the authority to regulate establishments that process poultry, and determine the safety, wholesomeness, and accurate labelling of such poultry products.

Section 409 of the FFDCA requires premarket approval of food additives, necessitating a petition that includes data and information establishing reasonable certainty that the substance is not harmful under the intended conditions of use. If a food additive is considered safe under the conditions of its intended use, the FDA promulgates a regulation specifying the conditions under which the additive may be safely used. Defining the term "food additive" involves two steps: the first step broadly includes any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of food. The second step, however, excludes from the definition of food additive substances that are generally recognized as safe.<sup>119</sup> Section 463 of the PPIA grants USDA the authority to regulate the use of substances generally recognized as safe, approved food additives, and sources of radiation to ensure that their use does not adulterate poultry products.<sup>120</sup> Under the tenets of the PPIA, and their implementing regulations, FDA and FSIS have been jointly empowered to determine the suitability of food ingredients and sources of radiation used in the production of poultry products. FDA determines the safety of substances and prescribes safe conditions of use, whereas FSIS determines the efficacy and suitability of food ingredients in poultry products.<sup>121</sup>

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<sup>116</sup> Proposal for a Council Regulation amending Regulation No 1234/2007 establishing a common organisation of agricultural markets as regards the marketing standards for poultry meat, COM(2008) 336 final, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0336:FIN:EN:PDF>

<sup>117</sup> USDA, "Livestock and Poultry: World Markets and Trade, October 2012, <http://www.thepoultrysite.com/reports/?id=985>

<sup>118</sup> Title 21, United States Code (21 U.S.C.), §§ 451 etsqq.

<sup>119</sup> Section 321(s) of the FFDCA, 21 U.S.C. § 321(s)).

<sup>120</sup> Section 463 PPIA reads: "(a) Storage and handling of poultry products; violation of regulations: The Secretary may by regulations prescribe conditions under which poultry products capable of use as human food, shall be stored or otherwise handled by any person engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, or importing, such articles, whenever the Secretary deems such action necessary to assure that such articles will not be adulterated or misbranded when delivered to the consumer. Violation of any such regulation is prohibited. (b) Other necessary rules and regulations: The Secretary shall promulgate such other rules and regulations as are necessary to carry out the provisions of this chapter."

<sup>121</sup> USDA, Related Documents for FSIS Directive 7120.1 - Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products,

In its suitability determinations, FSIS assesses the effectiveness of the ingredient in performing the intended purpose of use, and assesses whether the conditions of use result in an adulterated product, or one that misleads the consumer. Once a substance is considered safe and suitable for use in poultry products, it is added to a directive issued by FSIS, FSIS Directive 7120.1 on "Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products".<sup>122</sup> This directive, which is updated quarterly, identifies substances that have been approved in the Code of Federal Regulations (CFR) for use in meat, poultry, and egg products as food additives or are generally recognized as safe. It thereby provides inspection programme personnel with a current list of substances that may be used in the production of meat, poultry, and egg products.

Various PRTs are contained in this list, including chlorine dioxide, acidified sodium chlorite, trisodium phosphate, and peroxyacids. For each of these substances deemed "safe and suitable ingredients", the list specifies the substance, its use with regard to the product, permissible amounts or concentrations, and labelling requirements.

In the case of chlorine dioxide, for instance, it acknowledges its use in "water used in poultry processing" and requires that residual chlorine dioxide amounts as determined may not exceed a specified concentration of 3 parts per million. It also exempts the use of chlorine dioxide for the accepted conditions of use from any labelling requirements. Finally, where available, the list contains a reference to the formal document approving the substance as a "safe and suitable ingredient".

In 2002, the United States requested the European Commission to approve the use of four PRTs in the production of poultry intended for export to the European Union: chlorine dioxide, acidified sodium chlorite, trisodium phosphate, and peroxyacids. So far, the EU has not changed its import ban. On 16 January 2009, the United States requested formal consultations with the European Communities within the dispute settlement procedures of the WTO.<sup>123</sup> Some estimates calculate US losses due to the EU import restrictions to lie between \$200 million and \$300 million annually, given that exports to Europe have fallen by around 75% since the restrictions went into effect, and arguably more when accounting for EU enlargement (Johnson, 2012: 1f).

## Aviation

### EU

Since 1 January 2012, emissions from aircraft flying to and from airports in the EU have been covered by the European Union emissions trading system (EU ETS). Because this measure extends to foreign air carriers, it has given rise to substantial controversy across the Atlantic. Led by a coalition of US airlines, opposing nations have initiated litigation and threatened retaliatory measures in what has been termed "the world's first carbon trade war".<sup>124</sup> Yet the EU has countered that the measure was formally announced in a transparent manner long before the current conflict escalated, and that its actions are entirely consistent with its legally binding climate commitments and its long-term strategy to cut greenhouse gas emissions by 80 to 95 per cent compared with 1990 levels.

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<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/7000-series/safe-suitable-ingredients-related-document>

<sup>122</sup> USDA, FSIS Directive 7120.1 - Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products; changes to the list are published by the [Office of the Federal Register](#) in Title 9 of the [Code of Federal Regulations \(CFR\)](#), Part 424.

<sup>123</sup> European Communities — Certain Measures Affecting Poultry Meat and Poultry Meat Products from the United States, WT/DS389, [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds389\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds389_e.htm)

<sup>124</sup> Pilita Clark, Carbon Trade War Edges Nearer, Financial Times, 17 February 2012

As far back as 2005, the European Commission already affirmed that it was “not realistic” to expect timely and concerted international action on aviation emissions, hence calling for ambitious domestic and, if necessary, unilateral efforts.<sup>125</sup> Based on a series of public consultations and a feasibility study, the Commission submitted shortly thereafter a formal proposal for legislation to include aviation in the EU ETS.<sup>126</sup> In doing so, it expressly referred to an International Civil Aviation Organisation (ICAO) endorsement of open emissions trading and the possibility to incorporate emissions from international aviation into domestic trading systems.<sup>127</sup>

By late 2008, the European Parliament and Council passed a directive formally amending the EU ETS framework to include domestic and international aviation.<sup>128</sup> From 1 January 2012, virtually all flights arriving at or departing from an airport situated in the territory of Member States of the European Union or the European Economic Area have been covered by the EU ETS.

Only certain flight categories – such as flights for training, emergency services, or humanitarian and military objectives – as well as flights operating on low volume routes are exempted. In order to receive allowances, air carriers were required to submit an application by 30 June 2011, a deadline that airlines both within and outside the EU have met. Allowances were issued to airlines by 28 February 2012 through the administering Member State, which is the Member State that granted the operating license or, in the case of foreign airlines, the Member State “with the greatest estimated attributed aviation emissions from flights performed by that aircraft operator”.

Starting in 2013, covered airlines are under an obligation to surrender a sufficient number of allowances by 30 April of each year to cover their calculated CO<sub>2</sub> emissions from the previous year. Aside from surrendering the allowances obtained through free allocation or auction, air carriers can comply by acquiring allowances from other sectors covered by the EU ETS and – within specified limits – eligible credits from offset projects. It is this duty to surrender allowances on an annual basis which begets the climate benefits of the European measure, yet also poses a regulatory burden on airlines.

This perceived burden guided the Air Transport Association of America and three US airlines when, on 16 December 2009, they challenged the inclusion of aviation in the EU ETS before the High Court of Justice of England and Wales. Additional interveners – including several environmental groups – joined the proceedings on both sides and elevated the profile of this dispute. The High Court referred the central questions in the case to the ECJ on 8 July 2010 for a preliminary ruling. In a widely anticipated opinion delivered on 6 October 2011, the Advocate-General of the ECJ rejected all claims and stated that the inclusion of international aviation in the EU ETS was compatible with international law, did not infringe the sovereignty of other states or the freedom of the high seas, and respected applicable international agreements.<sup>129</sup>

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<sup>125</sup> European Commission, Communication on Reducing the Climate Change Impact of Aviation, COM(2005)459

<sup>126</sup> European Commission, Proposal for a Directive of the European Parliament and of the Council amending Directive 2003/87/EC so as to include aviation activities in the scheme for greenhouse gas emission allowance trading within the Community.

<sup>127</sup> International Civil Aviation Organisation (ICAO), Resolution A35-5.

<sup>128</sup> European Parliament and Council, Directive 2008/101/EC of 19 November 2008 amending Directive 2003/87/EC so as to Include Aviation Activities in the Scheme for Greenhouse Gas Emission Allowance Trading within the Community, OJ 2009 L 8/3.

<sup>129</sup> Opinion of Advocate General Kokott, 6 October 2011, Air Transport Association of America et al. v. Secretary of State for Energy and Climate Change, C-366/10.



Few observers were surprised when the ECJ upheld the Advocate-General's reasoning in its judgment of 21 December 2011, stating that the extension of the EU ETS to aviation infringes neither the principle of territoriality, nor the sovereignty of third countries; does not constitute a tax, fee or charge on fuel, which could be in breach of bilateral Air Transport Agreements in force across the Atlantic; and is consistent with provisions designed to prohibit discriminatory treatment between aircraft operators due to its uniform application to all flights departing or arriving from the European Union.<sup>130</sup>

Still, opposition to the unilateral EU efforts remained unabated. Given strong diplomatic pressure from foreign countries, including the United States and major emerging economies, the European Commission published a proposal on 12 November 2012 to exempt international flights to and from Europe from the compliance obligations under the EU ETS for one year (so-called "stop-the-clock" proposal) to allow for negotiation of a multilateral solution under the auspices of the ICAO. In the absence of a global deal, the compliance obligations would automatically resume after one year. Following passage in the European Parliament, the Council adopted the temporary derogation on 22 April 2013, formally deferring enforcement of the obligations of aircraft operators with respect to incoming and outgoing international flights under the EU ETS for 2012, including the requirement to report carbon emissions for flights between EU airports and third countries, and sanctions for failure to report or surrender allowances for 2012 emissions.<sup>131</sup>

On 5 September 2013, following presentation of a draft resolution by the ICAO Council setting a timeline for adoption of the modalities of a market-based mechanism for international aviation by 2016 and implementation by 2020, the EU offered to accept a compromise under which – rather than including emissions from the entire journey – international flights would in the meantime only be covered to the extent they use European airspace.<sup>132</sup>

## US

Almost from the outset, the plan to include international aviation in the EU ETS met with strong resistance from a number of foreign countries, including the US. Influenced by a coalition of air carriers concerned about the cost of complying with the European measure, both chambers of Congress adopted bills that exempt airlines from participating in the programme. Political deliberation preceding the passage of these bills reflected a widespread perception of the European measure among US policy makers. In the prevailing view, the inclusion of foreign airlines in the EU ETS represented a violation of US sovereignty and a tax imposed by the EU on Americans to address climate change, in itself a phenomenon contested by many in the United States.<sup>133</sup>

<sup>130</sup> ECJ Judgment of 11 December 2011, *Air Transport Association of America et al. v. Secretary of State for Energy and Climate Change*, C-366/10.

<sup>131</sup> Press release, *The Council Adopts Decision on Temporary Derogation from the EU Emissions Trading System Directive*, 22 April 2013, [http://www.consilium.europa.eu/uedocs/cms\\_data/docs/pressdata/en/envir/136892.pdf](http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/envir/136892.pdf)

<sup>132</sup> Reuters, "EU Concession in Aviation Emissions Row Eases Trade Concern", 5 September 2013, <http://www.reuters.com/article/2013/09/05/eu-aviation-idUSL6N0H12YK20130905>; ENDS, *EU Defends „Disappointing“ ICAO Plan on Emissions*, 5 September 2013.

<sup>133</sup> As Senator John Thune, sponsor of one of the bills, described it, his bill was designed to "ensure that U.S. air carriers and passengers will not be paying down European debt through this illegal tax ... and prevent the EU's unlawful attack on American sovereignty", Thune, "Senate Passes Thune Bill to Block European Airline Tax on U.S. Carriers, Passengers"; although milder in wording, this general sentiment also underlay a letter signed by senior representatives of the Administration – Secretary of State Hillary Clinton and Secretary of Transportation Ray LaHood – sent to the President of the European Commission on 16 December 2011, see Department of State, Letter by Secretary of State, Hillary Clinton, and Secretary of Transportation, Ray LaHood, 16 Dec. 16, 2011, <http://www.nbaa.org/ops/environment/eu-ets/20111216-eu-ets-us-state-department-clinton.pdf>

In September 2012, the US Senate unanimously passed a legislative proposal (a “bill”) prohibiting US civil aircraft operators from taking part in EU ETS, but requiring a public hearing and prior determination that a prohibition would be in the public interest. Such a determination needs to consider various factors, including the impact on US consumers, carriers, and operators; US interests in economic, energy, and environmental security; and U.S foreign relations and international commitments. Additionally, the bill requires the executive “to hold operators of civil aircraft of the United States harmless from the emissions trading scheme”, which, while unclear, may be interpreted as an indemnification of US air carriers; at the same time, it prohibits the use of tax revenue for the payment of any penalties imposed on airlines under the EU ETS.<sup>134</sup> A further provision enables the Secretary of Transportation to reassess the previous determination if the EU ETS is altered, an international agreement is reached, or formal US rulemaking addresses aviation emissions. And finally, the bill encourages negotiations to pursue an international approach to addressing aviation emissions. The Senate bill was subsequently passed by the House of Representatives and signed into law by the President on 27 November 2012.<sup>135</sup>

Meanwhile, the US imposes no binding climate change mitigation requirements on domestic or international aviation. Some observers have contended that the US EPA could impose sufficiently robust requirements under the Clean Air Act to address emissions from air travel, with initial studies of the powers afforded to the EPA suggesting that it can regulate aviation emissions and has broad discretion over scope, stringency, and the type of regulatory mechanism. While a performance standard may be the default instrument under the Clean Air Act, the EPA could also explore market-based tools to increase the cost-effectiveness of its regulatory framework (Richardson, 2013).

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<sup>134</sup> S. 1956, European Union Emissions Trading Scheme Prohibition Act of 2011, Sec. 3, 112th Congress, 2nd Session. 22 September 2012.

<sup>135</sup> Public Law 112-200, European Union Emissions Trading Scheme Prohibition Act of 2011, 112th Congress, 2<sup>nd</sup> Session. 126 Stat. 1477. 27 November 2012.

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**NOTES**





DIRECTORATE-GENERAL FOR INTERNAL POLICIES

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