



DIRECTORATE-GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT
ECONOMIC AND SCIENTIFIC POLICY **A**

Economic and Monetary Affairs

Employment and Social Affairs

**Environment, Public Health
and Food Safety**

Industry, Research and Energy

Internal Market and Consumer Protection



**ENVI Relevant Legislative
Areas of the EU-US Trade
and Investment Partnership
Negotiations (TTIP)**

Study for the ENVI Committee



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

ENVI Relevant Legislative Areas of the EU-US Trade and Investment Partnership Negotiations (TTIP)

STUDY

Abstract

This study, prepared by Policy Department A, aims to support Members of the Committee on Environment, Public Health and Food Safety (ENVI) in monitoring on-going negotiations for a Transatlantic Trade and Investment Partnership (TTIP). It analyses the main differences between EU and US legislation in eight areas, namely: human medicines and medical devices, cosmetics, food and nutrition, sanitary and phyto-sanitary, nanomaterials, cloning, raw materials and energy, and motor vehicles. Existing collaboration between the EU and US, progress already achieved in the negotiations and potential future developments in these areas are also addressed.

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

AUTHORS

Shailendra Mudgal, BIO by Deloitte
Katherine Salès, BIO by Deloitte
Alice Landowski, BIO by Deloitte
Otto Kern, BIO by Deloitte
Juliette Mansard, BIO by Deloitte
Christiane Gerstetter, Ecologic Institute
Max Grünig, Ecologic Institute
Elizabeth Dooley, Ecologic Institute
Elizabeth Tedsen, Ecologic Institute
Martin Nesbit, Institute for European Environmental Policy
Kamila Paquel, Institute for European Environmental Policy
Sirini Withana, Institute for European Environmental Policy

RESPONSIBLE ADMINISTRATOR

Dagmara Stoerring
Policy Department Economic and Scientific Policy
European Parliament
B-1047 Brussels
E-mail: Poldep-Economy-Science@europarl.europa.eu

LINGUISTIC VERSIONS

Original: EN

ABOUT THE EDITOR

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To contact Policy Department A or to subscribe to its newsletter please write to:
Poldep-Economy-Science@ep.europa.eu

Manuscript completed in October 2014
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LIST OF ABBREVIATIONS

APHIS	Animal and Plant Health Inspection Service
BEUC	The European Consumer Organisation
CAA	Clean Air Act
CAFE	Corporate Average Fuel Economy
CBI	Confidential Business Information
CDER	Center for Drug Evaluation and Research (US)
CE	European Conformity
CFR	Code of Federal Regulations (US)
CLP	Classification, Labelling and Packaging
CO₂	Carbon Dioxide
CPSR	Cosmetic Product Safety Report
DG ENTR	Directorate General Enterprise and Industry (EU)
DG RTD	Directorate General Research and Innovation (EU)
DG SANCO	Directorate General Health and Consumers (EU)
DOE	Department of Energy (US)
EA	Environmental Assessment
EC	European Commission
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EIS	Environmental Impact Statement
EMA	European Medicines Agency
EN	European Standards
ENVI Committee	European Parliament Committee on Environment, Public Health and Food Safety

EP	European Parliament
EPA	Environmental Protection Agency (US)
EPAR	European Public Assessment Report
ERA	Environmental Risk Assessment
EU	European Union
Eudamed	European databank for medical devices
FAO	Food and Agriculture Organisation of the United Nations
FDA	Food and Drug Administration (US)
FD&C Act	Federal Food, Drug, and Cosmetic Act (US)
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act (US)
FOI Act	Freedom of Information Act (US)
FPLA	Fair Packaging and Labelling Act (US)
FQPA	Food Quality Protection Act (US)
FR	Federal Register (US)
FSIS	Food Safety and Inspection Service (US)
FSMA	Food Safety Modernisation Act (US)
FTA	Free Trade Agreement
FQD	Fuel Quality Directive (EU)
GDP	Gross Domestic Product
GHG	Greenhouse gases
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practice
GRAS	Generally Recognised As Safe
HACCP	Hazard Analysis and Critical Control Point
ILUC	Indirect Land Use Change
IPM	Integrated Pest Management

IPPC	International Plant Protection Conference
LCA	Life Cycle Assessment
LCFS	Low Carbon Fuel Standard
LCV	Light Commercial Vehicles
LEV	Low Emission Vehicle
LNG	Liquefied Natural Gas
LPG	Liquefied Petroleum Gas
MA	Marketing Authorisation
MDCG	Medical Device Coordination Group (EU)
MRA	Mutual Recognition Agreement
MS	Member State of the EU
MY	Model Year
NB	Notified Body
NDA	New Drug Application
NEPA	National Environmental Policy Act (US)
NFR	Novel Food Regulation (EU)
NGO	Non Governmental Organisation
NM	Nanomaterial
NMSP	Nanoscale Materials Stewardship Program (US)
NOAEL	No Observed Adverse Effect Level
OIE	World Organisation for Animal Health (ex- <i>Office International des Epizooties</i>)
PMA	Premarket Approval
PMN	Pre-Manufacture Notice

- PPP** Plant Protection Product
- REACH** Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006)
- RFS2** Renewable Fuel Standard 2 (US)
- RMM** Risk Mitigation Measure
- SCCS** Scientific Committee for Consumer Safety (EU)
- SPS** Sanitary and Phyto-Sanitary
- SNUN** Significant New Use Notice
- SNUR** Significant New Use Rules
- SUE** Serious Undesirable Effect
- TSCA** Toxic Substances Control Act (US)
- TSIA** Trade Sustainability Impact Assessment
- TTIP** Transatlantic Trade and Investment Partnership
- UN** United Nations
- UNECE** United Nations Economic Commission for Europe
- US** United States of America
- U.S.C.** United States Code
- USDA** United States Department of Agriculture
- VCRP** Voluntary Cosmetic Registration Program (US)
- VOC** Volatile Organic Compound
- WTO** World Trade Organisation

EXECUTIVE SUMMARY

This study aims to provide the members of the Committee on Environment, Public Health and Food Safety (ENVI Committee) with the needed expertise to monitor the ongoing negotiations between the United States (US) Administration and the European Commission (EC) for a Transatlantic Trade and Investment Partnership (TTIP) agreement. It is a follow-up to a 2013 study on "Legal Implications of TTIP for the *Acquis Communautaire* in ENVI Relevant Sectors¹" which had been commissioned by the European Parliament (EP) ENVI Committee.

The stated objective of TTIP negotiations (and subsequent agreement), which were launched in July 2013, is to facilitate commercial exchanges of goods and services between both sides of the Atlantic and to enhance investments on each side. This is to be achieved through the removal of trade barriers, which include tariffs and non-tariff measures such as differences in regulations. There are however substantial regulatory differences between the EU and the US which usually reflect differing concerns, focus or approaches (e.g. different value judgments, policy objectives, approaches to risk analysis). TTIP negotiations therefore raise concerns, notably among members of civil society, that potential harmonisation that could result from these negotiations may undermine the levels of protection of public health and safety, and the environment. Nonetheless, in certain areas some convergence may be possible without undermining the respective levels of protection in the EU and the US. The EC has affirmed that nothing would be done to lower or endanger these levels of protection.

Against this background, this study compares and highlights the main differences in key EU and US legislation in eight TTIP-relevant areas: medicinal products for human use and medical devices; cosmetics; food and nutrition; sanitary and phyto-sanitary (SPS); nanomaterials (NMs); cloning; raw materials and energy; and motor vehicles. In each of these areas, the study focuses on two key issues identified in cooperation with the EP based on the study team's expert judgement of important differences between EU and US legislation and their relevance for the TTIP.

Medicines for human use and medical devices

In the EU, the marketing authorisation (MA) process for human pharmaceuticals is often decentralised, as the applicant may choose between four procedures (depending notably on the geographical area to be covered by the MA), only one of which is centralised at the level of the EU. By contrast, the marketing approval system in the US is fully centralised through the Food and Drug Administration (FDA). Applicants are required to submit an environmental assessment as part of their application dossier. In the EU system, an environmental risk assessment (ERA) is required; but it is not part of the risk-benefit analysis and does not impact the granting of the MA. By contrast, in the US, the FDA could consider beginning an action to withdraw the approval based on comments made on the environmental impact statement (EIS) published when the environmental assessment (EA) of the pharmaceutical shows the existence of a potential impact on the environment. Information included in the application dossier is not freely available either in the EU or the US as it may be considered confidential business information or a trade secret; this applies notably to the ERA (EU) and the EA (US). However, the distinction between confidential

¹ EP (2013), Ecologic Institute and BIO Intelligence Service, Legal Implications of TTIP for the *Acquis Communautaire* in ENVI Relevant Sectors, IP/A/ENVI/ST/2013-09, PE 507.492; available at: [http://www.europarl.europa.eu/ReqData/etudes/etudes/join/2013/507492/IPOLENVI_ET\(2013\)507492_EN.pdf](http://www.europarl.europa.eu/ReqData/etudes/etudes/join/2013/507492/IPOLENVI_ET(2013)507492_EN.pdf).

and non-confidential information is clearer and more harmonised in the US than it is in the EU.

In the US, the marketing approval system for medical devices is also centralised via two main pathways (leading to “approval” or “clearance”), whereas the system is decentralised in the EU, with only one pathway: the European Conformity (CE) mark which applies to all devices. In the US, medical devices are subject to rules similar to those applicable to pharmaceuticals regarding environmental assessment and EIS, whereas in the EU an ERA is not required to be carried out. Finally, information on medical devices may not be freely and publicly accessible in both systems. For instance, in the EU a centralised European databank for medical devices (Eudamed) has been developed which is only accessible to Member States’ competent authorities, not to the public. By contrast, in the US some information (e.g. safety and effectiveness data, protocol for a test or study) must be made publicly available by the FDA, after deletion of information that constitutes a trade secret or confidential commercial or financial information.

Cosmetics

EU legislation imposes notification and registration requirements concerning cosmetic substances and finished products on the EU market. In addition, all substances contained in cosmetic products are subject to a strict safety assessment prior to being authorised by the EC for use in cosmetics. In the US, manufacturers are not required to register their cosmetic establishment or their products, and safety testing is not mandatory. Another important difference relates to animal testing, which is strictly banned in the EU while US legislation allows animal testing under particular circumstances. Also, the list of substances whose use in cosmetics is prohibited broadly differs between the EU and US: more than 1 300 ingredients are banned in the EU whereas less than twenty are prohibited in the US.

Food and nutrition

Traceability systems are an important aspect of food safety. While the EU uses a “farm to fork” approach covering all stages of the supply chain, the US focuses on registered facilities, largely excluding the beginning and end of the supply chain. However, the US system may undergo significant changes in the near future, potentially becoming a more comprehensive traceability scheme like the EU system. There is nonetheless an important difference in the approach to recordkeeping: the EU has adopted an “obligation of results” rather than an “obligation of means” system whereas the envisaged US system would likely be based on more rigid requirements. Another main regulatory difference between the US and EU is the approach taken to risk analysis for food safety. It is based on the precautionary principle in the EU (allowing for action in cases of scientific uncertainty) while the US approach requires robust scientific evidence of harmful effects, before regulatory action is taken. Finally, regarding nutrition and health claim labelling, the evaluation of the submitted evidence is required by both the European Food Safety Authority (EFSA) and the FDA. However, while the US only considers whether there is significant scientific agreement, the EU considers scientific evidence as well as stakeholder and consumer opinion before allowing products to be labelled. A difference is also that the US allows qualified health claims to be placed on food packages even if the significant scientific agreement standard cannot be met, as long as there is “credible” science to support the claim and a qualifying statement is added.

SPS measures

As part of the approval process of plant protection products (PPPs) for marketing and use, both the EU and US systems require an assessment of the potential impacts of these products on the environment, animal and human health. One difference is that the US also takes account of economic costs and benefits of the use of PPPs when considering a PPP approval. In addition, while the EU expects independent laboratory studies, companies applying in the US are allowed to submit their own studies. Another difference is that a marketing authorisation must be renewed every 10 years in the EU, but only every 15 years in the US. When the assessment leads to findings of adverse effects, risk mitigation measures will be imposed to prevent these adverse effects; however, the approach taken differs: the EU applies the precautionary principle, whereas the US requires robust scientific evidence of harmful effects.

Nanomaterials

In the EU and the US, there is no specific legislation on NMs. Rules for the use of NMs or products containing NMs are implicitly included in general regulations on chemicals. These regulations are Regulation (EC) No 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) in the EU, and the Toxic Substances Control Act (TSCA) in the US. The TSCA is more flexible regarding the submission of safety data and the use restrictions than REACH. Furthermore, where the US does not include requirements for NMs in other regulations, the EU expressly includes such requirements in product-specific legislation, notably notification and labelling rules for NMs contained in cosmetics, food additives and biocides. A commonly agreed definition of NM at international level and dedicated legislation for NMs is under development on either side of the Atlantic, with ongoing public consultations, workshops, research programmes, etc. It is interesting to note that some EU MSs have already implemented NM registration rules within their own territory.

Cloning

In the EU, food from cloned animals currently falls under the Novel Food Regulation (NFR), which requires food products from cloned animals to undergo pre-market approval; however, the provisions contained in this regulation do not extend to food from the offspring of cloned animals. The NFR includes labelling requirements for novel food that would also extend to products from cloned animals. In 2013, the EC proposed new legislation which would prohibit the marketing of products, including imported products, from cloned animals but not products from their progeny. In the US, no binding pre-market approval or labelling requirements exist. Such requirements are unlikely to be adopted as the FDA, following a multi-year assessment of cloning risks, considered that products from cloned animals (cow, pig and goat) or their offspring are as safe as food from conventionally-bred animals. However, the industry has been requested to continue to follow a voluntary moratorium against putting cloned animal products on the market. The lack of US monitoring and labelling of cloned animal products could create serious difficulties for oversight of imports of these products to the EU and other markets.

Raw materials and energy

The study looked at shale gas exploitation (“fracking”) and fuel quality standards. While there are significant differences between the EU and US in regulatory standards for shale gas exploration and exploitation, both lack a single economy-wide regulatory framework for unconventional gas and specific economy-wide binding rules on the environmental impacts of shale gas exploitation. The harmonisation of regulatory standards in response

to TTIP appears unlikely in the absence of specific standards at EU or US level, however the 2014 Commission recommendation could be a potential starting point for a discussion on approximation of legislation. EU and US regulation also differ in terms of fuel carbon intensity standards and legislative approaches to imports to the EU of liquefied natural gas derived from US shale gas supplies. While increased liquefied natural gas imports are viewed by some as a potential contribution to improved EU energy security, concerns have also been expressed by US environmental non-governmental organisations that an increase in transatlantic trade in fuels could lead to increased production and resulting environmental impacts, including impacts to air and water quality and greenhouse gas emissions from shale gas extraction as well as from the energy intensive liquefaction process and transport. Fuel quality legislation, and in particular the need for EU rules on calculating the GHG intensity of fossil fuels, is likely to remain a controversial topic on the TTIP agenda.

Motor vehicles

Regulations in the EU and the US strive for environmental protection and fuel efficiency. However, there remain a number of differences regarding technical environmental standards for motor vehicles in the following areas: CO₂ reduction targets (which are more stringent in the EU), emission standards (which are more stringent in the EU for CO₂ emissions), fuel economy standard, mutual recognition through the United Nations Economic Commission for Europe (UNECE), fuel/ignition type differentiation, limits on nitrogen oxides emissions from diesel engines (which are more stringent in the US), and testing methods. The EU and US have already agreed on future developments within TTIP negotiations in this area: for instance, they intend to further use the UNECE platform to strengthen international rules and establish a list of converging regulations.

The analysis in this study of key issues within eight TTIP-relevant areas suggests that the degree of divergence between the regulatory systems of the EU and the US, and thus the development of future requirements and potential collaboration, varies depending on the area concerned. In some cases (cosmetics, cloning), the differences are so significant that they are unlikely to be bridged. Differences that result from diverging approaches to risk analysis (e.g. a precautionary approach in the EU vs a "sound-science" approach in the US) including in the areas of food safety and SPS may also further complicate a convergence of regulations. In areas where differences between EU and US regulatory systems are mainly of a technical nature (e.g. technical environmental standards for motor vehicles), greater convergence could potentially be achieved through increased technical cooperation or mutual recognition of environmental regulations. Finally, in areas where there are currently no binding regulations on either side of the Atlantic (e.g. nanomaterials), convergence may also be easier to achieve through scientific and technical cooperation and better coordination of EU and US regulators.

1. INTRODUCTION TO THE TTIP NEGOTIATIONS

In February 2013, the European Union (EU) and the United States of America (US) started the procedures necessary for initiating formal negotiations on a free trade agreement (FTA), referred to as the “Transatlantic Trade and Investment Partnership” (TTIP)². The first round of negotiations took place in Washington D.C. in July 2013, the sixth round of negotiations took place in Brussels in July 2014³, and the seventh round ended on 3 October 2013⁴. The TTIP negotiations aim to facilitate commercial exchanges of goods and services between both sides of the Atlantic and to enhance investments on each side by removing trade barriers. These trade barriers include tariffs and non-tariff measures such as differences in technical regulations, standards and approval procedures which are economically significant⁵. In general, “studies suggest that between two thirds and four fifths of the gains from a future agreement would come from cutting red tape and having more coordination between regulators”, according to the European Commission (EC)⁶. In particular, a study carried out by the Centre for Economic Policy Research, London, on the potential effects of TTIP estimated that – in case of an ambitious scenario (decrease by 25 % of non-tariff barriers related costs and full tariff removal) – the agreement could provide economic benefits of EUR 119 billion a year for the EU and EUR 95 billion a year for the US. It is also assumed that TTIP would lead to a rise in total EU exports of 6 % and in total US exports of 8 %⁷. If agreed, TTIP would represent the biggest international trade agreement ever made.

However, it is important to note that, although considered trade barriers, the substantial regulatory differences between the EU and the US may reflect differing concerns, focus, and approaches on each side of the Atlantic, such as, for instance, different value judgments, policy objectives, or approaches to risk analysis. A strong example of such regulatory differences is the use of the precautionary principle under EU legislation which applies to situations where there is a suspected risk that an action or policy may cause harm to the public or the environment although there is a lack of scientific consensus as to the harmful nature of such action or policy. According to the EU’s interpretation of the precautionary principle, regulatory action (ranging from further research or enhancing public information to product prohibitions) may be taken in cases of scientific uncertainty⁸. By contrast, in the US, through the so-called “sound-science” approach, sound scientific evidence of the existence of harm is generally required before regulatory action is taken. It should be noted that these approaches are not hard and fast rules, but hold true as general descriptions of the regulatory and policy-making culture on both sides of the Atlantic.

² See EU Council, Council approves launch of trade and investment negotiations with the United States, Press release, Luxembourg, 14 June 2013; available at: http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/EN/foraff/137485.pdf.

³ See EC, State of play of TTIP negotiations after the 6th round, 29 July 2014; available at: http://trade.ec.europa.eu/doclib/docs/2014/july/tradoc_152699.pdf.

⁴ See <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1154> and <http://ec.europa.eu/trade/policy/in-focus/ttip/>.

⁵ See EC DG TRADE, What is the Transatlantic Trade and Investment Partnership (TTIP)?; available at: <http://ec.europa.eu/trade/policy/in-focus/ttip/about-ttip/>.

⁶ EC DG TRADE, Transatlantic Trade and Investment Partnership, The Regulatory Part, September 2013; available at: http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151605.pdf.

⁷ Centre for Economic Policy Research, London. Reducing Trans-Atlantic Barriers to Trade and Investment; Final Project Report, March 2013. Prepared for the EC DG TRADE under Prepared under implementing Framework Contract TRADE10/A2/A16; available at: http://trade.ec.europa.eu/doclib/docs/2013/march/tradoc_150737.pdf.

⁸ On the precautionary principle, see e.g. European Council, Presidency Conclusions, Nice European Council Meeting, 7, 8 and 9 December 2000; available at: http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/ec/00400-r1.%20ann.en0.htm.

In view of such differences, there is fear that harmonisation that may result from TTIP negotiations would undermine levels of protection of, notably, public health and safety, and the environment⁹. However, in some areas, some convergence may be possible without undermining the respective levels of protection in the EU and the US. The EU's Chief TTIP Negotiator indicated, at the end of the sixth negotiating round and confirmed at the end of the seventh round of talks, that "nothing will be done which could lower or endanger the protection of the environment, health, safety, consumers or any other public policy goals pursued by the EU and US regulators"¹⁰. Furthermore, negotiators have noted that shared EU-US regulatory approaches are more likely to be followed globally, thereby raising rather than lowering standards⁶. The EC nonetheless recognises that "the result in all negotiations is a compromise – so by definition we can't predict exactly the final outcome"⁶. However, the EC reaffirmed that both sides have agreed to aim "to reduce unnecessary costs and administrative delays stemming from regulation, while achieving the levels of health, safety, and environmental protection that each side deems appropriate"¹¹.

With the aim of cutting unnecessary red tape to reduce the costs of doing business and making EU and US regulations more effective through closer cooperation,⁶ TTIP may have an impact on both existing and future regulations as noted in EC documents:

- Regarding existing regulations, three possibilities have been identified:
 - to formally recognise that some regulations have broadly the same effect, and hence complying with one set of rules would be considered sufficient to sell in both markets (e.g. car safety);
 - to move regulation within the US and the EU closer to internationally agreed ways of solving the problem at hand (e.g. classification and labelling of chemicals); and
 - where EU and US regulations are very different, regulators could cooperate more on how they put the regulation into practice (e.g. safety assessments of the same chemicals)⁶.
- Regarding future regulations, the talks on TTIP aim to ensure that regulators coordinate better in the future when they design regulation for new products or update regulation of existing products (e.g. on electric cars), so that EU and US regulations gradually become more compatible⁶.

In this framework, the EC commissioned a Trade Sustainability Impact Assessment (TSIA) to support the TTIP negotiations. The TSIA study is under way and should be finalised by the end of the year¹². The objective of the TSIA is to assess the potential impacts of the TTIP provisions on economic, social and environmental issues in the EU and the US.

⁹ See e.g. The European Consumer Organisation (BEUC), Transatlantic Trade and Investment Partnership – Questions & Answers; available at: http://www.beuc.eu/publications/x2013_093_qa-transatlantic-trade-and-investment-partnership.pdf.

¹⁰ EU's Chief TTIP Negotiator's statement at the end of the sixth round of negotiations, Press release, Brussels, 18 July 2014; available at: <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1132&title=EU-US-trade-%E2%80%93-latest-round-of-talks-on-transatlantic-trade-pact-ends-in-Brussels>; "EU-US trade – 7th round of talks on transatlantic trade pact ends in the US"; available at: <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1158>.

¹¹ High-Level Working Group on Growth and Jobs, Final Report, February 11, 2013. Cited in EC DG TRADE, Transatlantic Trade and Investment Partnership, The Regulatory Part, September 2013, p. 5.

¹² See <http://www.trade-sia.com/ttip/>.

It includes an overall analysis on a macroeconomic level, a sector-specific analysis on a number of sectors¹³, as well as consultations and interaction with stakeholders.

The involvement of stakeholders, in particular from the civil society, is of primary importance in the TTIP negotiations. As previously indicated, EU and US citizens have concerns on regulatory cooperation and harmonisation and the perceived risk of a lowering of the standards of protection for the interest of trade. According to the EC, actions to ensure citizens are allowed to express their viewpoints include public consultations and events dedicated to flow and exchanges of information between representatives of non-governmental organisations (NGOs) and trade unions, consumer protection organisations, independent experts, industry bodies, firms and governments¹⁴.

Following the sixth round of negotiations, of the many sectors that fall within the scope of TTIP negotiations, those currently under discussion are: textiles, chemicals, pharmaceuticals, cosmetics, medical devices, pesticides, cars, engineering and information and communication technology.³ In addition, TTIP negotiations also contemplate, among others, a specific chapter on sanitary and phyto-sanitary (SPS) measures, as well as a future chapter dedicated to energy and raw materials.³ The seventh round of negotiations ended in early October and, according to information available at the time of writing this report, it focused on all regulatory elements of TTIP, whether horizontal disciplines such as SPS or specific sectors identified in previous rounds (e.g. pharmaceuticals, cars), as well as among others energy and raw materials¹⁵. As regards horizontal disciplines, negotiators are engaged in discussions based on textual proposals; whereas on specific sectors, negotiators focus on technical work to identify outcomes that would save unnecessary duplications¹⁵.

This study on ENVI relevant legislative areas of the EU-US trade and investment partnership negotiations complements a previous study commissioned by the European Parliament (EP) Committee on Environment, Public Health and Food Safety (ENVI Committee) in 2013 on "Legal Implications of TTIP for the *Acquis Communautaire* in ENVI Relevant Sectors"¹⁶. This first study discussed the potential impact of the TTIP on the EU *acquis*, by highlighting the main differences in EU and US legislation in four policy areas: genetically modified organisms (GMOs), regulation of toxic substances, chlorinated poultry and aviation. The 2013 study demonstrated that, overall, EU regulation in these four fields was more comprehensive and/or more stringent than in the US, with the private sector facing fewer requirements and benefiting from greater flexibility in the US. In the areas of GMOs and toxic substances, the study concluded that there is greater transparency and public access to information in the EU than in the US.

The objective of this follow-up study is to provide the members of the ENVI Committee with the needed expertise to monitor the ongoing negotiations for a TTIP launched by the US Administration and the EC in 2013.

¹³ Ecorys, Trade Sustainability Impact Assessment on the Transatlantic Trade and Investment Partnership (TTIP) between the European Union and the United States of America. Final Inception Report, 28 April 2014; available at: <http://www.trade-sia.com/ttip/wp-content/uploads/sites/6/2014/06/TSIA-TTIP-Final-Inception-Report-publish2506.pdf>.

¹⁴ Transparency in TTIP negotiations, "Towards an EU-US trade deal – Making trade work for you – We're listening and engaging you", 28 March 2014, http://trade.ec.europa.eu/doclib/docs/2014/march/tradoc_152276.pdf.

¹⁵ EU's Chief TTIP Negotiator's statement at the end of the seventh round of negotiations, Press release, Washington, D.C., 3 October 2014; available at: <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1158>.

¹⁶ EP (2013), Ecologic Institute and BIO Intelligence Service, Legal Implications of TTIP for the *Acquis Communautaire* in ENVI Relevant Sectors, IP/A/ENVI/ST/2013-09, PE 507.492; available at: [http://www.europarl.europa.eu/ReqData/etudes/etudes/join/2013/507492/IPOL_ENVI_ET\(2013\)507492_EN.pdf](http://www.europarl.europa.eu/ReqData/etudes/etudes/join/2013/507492/IPOL_ENVI_ET(2013)507492_EN.pdf).

This study compares and highlights the main differences in key EU and US legislation in eight ENVI-relevant areas to be tackled in the negotiations on TTIP. The areas covered in the study are: medicines for human use and medical devices; cosmetics; food and nutrition; SPS; nanomaterials (NMs); cloning; raw materials and energy; and motor vehicles.

For each of these areas, the analysis in the study focuses on two key issues that have been identified in agreement with the EP. The identification of these issues is based on the expert judgement of the study team of those issues where there is the most significant divergence between EU and US legislation, which are of relevance for the TTIP negotiations and fall within the responsibilities of the ENVI Committee.

The analysis in this study is based mainly on existing literature (secondary sources) with specific reference to and analysis of original legal texts where relevant to ensure a comprehensive assessment. Where relevant, the study also refers to progress achieved in each area as of the end of the sixth round of TTIP negotiations. The state of play in each area may have subsequently evolved following the seventh round of negotiations which ended on 3 October 2014, however this is not reflected in the study as no specific information was available at the time of writing¹⁷.

¹⁷ See <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1154> and <http://ec.europa.eu/trade/policy/in-focus/ttip/>.

2. MEDICINES FOR HUMAN USE AND MEDICAL DEVICES

KEY FINDINGS

- The marketing authorisation process for human pharmaceuticals is highly centralised in the US (through the Food and Drug Administration (FDA)) whereas it is often decentralised in the EU (four procedures exist: centralised, decentralised, mutual recognition and national procedures).
- An environmental assessment is required in the medicinal product application dossier in both the EU and the US. However, the Environmental Risk Assessment (ERA) is not part of the risk-benefit analysis in the EU, whereas in the US, post-approval comments made to an Environmental Impact Statement (EIS) may be used by the FDA to consider withdrawing the approval.
- Information contained in the marketing application may be considered as confidential or non-confidential. The distinction appears clearer under US law than EU legislation.
- For medical devices, the marketing approval system is centralised in the US (through the FDA) via two main pathways (leading to "approval" or "clearance"), whereas the system is decentralised in the EU (through Notified Bodies (NBs)), with only one CE mark which applies to all medical devices. The US system is stricter than the EU system.
- In the US, medical devices are subject to rules similar to those applicable to pharmaceuticals regarding environmental assessment and EIS, whereas in the EU there is no specific requirement that an ERA be carried out for such devices.
- The EU has a centralised European databank for medical devices (Eudamed) accessible by MS competent authorities but not by the public.

The analysis of the main differences between the EU and US legislation in the fields of medicinal products for human use and medical devices focuses on two key issues: the marketing authorisation (MA) process, with a focus on risk assessment (in particular environmental assessment); and confidential business information (CBI).

A Mutual Recognition Agreement (MRA) was signed in 1998 between the US and the EU, focusing on specific areas including medical devices and pharmaceutical Good Manufacturing Practices (GMPs)¹⁸. It aims to harmonise the regulation with regards to the clearance of medical devices between the US and EU. The MRA recognises the importance of considering health, safety, environmental and consumer protection requirements of the US and the EU. However, regulatory cooperation between the US and the EU on medical devices is taking place "to facilitate the sharing of documents and/or information related to assuring the safety, quality, and efficacy, as appropriate, of medical devices" (e.g. advanced drafts of laws, regulations, guidance documents, etc.; post-marketing data and information that could have an impact on the public health; information reports and

¹⁸ Council Decision 1999/78/EC of 22 June 1998 on the conclusion of an Agreement on Mutual Recognition between the European Community and the United States of America (OJ L 31, 4.02.1999, p.1), as amended by Council Decision 2002/803/EC of 8.10.2002 (OJ L 278, 16.10.2002, p.22). Entered into force in December 1998.

product sample test results)¹⁹; the Annex on medical devices in the MRA is regarded as superseded by this cooperation²⁰. Regarding medicines, regulatory cooperation for the sharing of documents and/or information has also been taking place on matters related to ensuring the safety, quality, and efficacy of pharmaceutical products, with notably an Implementation Plan for Medicinal Products for Human Use and a Pilot Programme for scientific advice²¹. In the case of drug approvals, past EU-US cooperation has contributed to reducing unnecessary duplication of tests and, hence, reducing costs for applicants²².

As of the end of the sixth round of negotiations TTIP discussions regarding pharmaceuticals have focused on GMPs and Biosimilars. The US and EU also plan on intensifying technical work to examine the scope for mutual reliance/recognition of the other party's inspections of manufacturing facilities. Regarding medical devices, discussions have so far focused on Unique Device Identification, Regulatory Product Submission and Medical Devices Single Audit Programme²³. This state of play may nevertheless have evolved following the seventh round of negotiations which ended on 3 October 2014²⁴.

2.1. Legislation in the EU

The MA of medicinal products for human use is governed mainly by Directive 2011/83/EC of 6 November 2011²⁵ and Regulation (EC) No 726/2004 of 31 March 2004²⁶, as amended.

Based on the New Approach²⁷ developed by the EU ("an innovative methodology of technical harmonization designed to remove barriers to trade and facilitate the free movement of goods with[in] the [EU]")²⁸ rules related to the safety and performance of medical devices were harmonised in the EU. It allowed the establishment of a new impetus concerning medical devices for Europe due to a new core legal framework consisting of three Directives (Directive 90/385/EEC regarding active implantable medical devices, Directive 98/42/EEC regarding medical devices, and Directive 98/79/EC regarding *in vitro*

¹⁹ FDA-DG Enterprise cooperation arrangement, July 2007, through FDA and DG Enterprise Letters of 2 July 2007; http://www.ustr.gov/archive/assets/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/asset_upload_file267_13263.pdf and http://www.ustr.gov/archive/assets/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/asset_upload_file840_13261.pdf.

²⁰ EC DG TRADE, Trade issues, Technical Barriers to Trade, Mutual Recognition Agreements and Agreements on Conformity Assessment and Acceptance of Industrial Products, MRA Newsletter No. 6, April 2014; available at: http://trade.ec.europa.eu/doclib/docs/2014/april/tradoc_152342.pdf.

²¹ See http://www.ustr.gov/archive/World_Regions/Europe_Middle_East/Europe/US_EU_Regulatory_Cooperation/Section_Index.html.

²² EC DG TRADE, Transatlantic Trade and Investment Partnership, The Regulatory Part, September 2013; available at: http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151605.pdf.

²³ See sections 2.4.3 (pharmaceuticals) and 2.4.4 (medical devices) of the State of Play of TTIP negotiations after the 6th round, 29 July 2014, available at: http://trade.ec.europa.eu/doclib/docs/2014/july/tradoc_152699.pdf

²⁴ No specific information was available at the time of writing this report; see <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1154> and <http://ec.europa.eu/trade/policy/in-focus/ttip/>.

²⁵ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended, OJ L 311, 28.11.2001, pp.67-128.

²⁶ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as amended, OJ L 136, 30.4.2004, pp.1-33.

²⁷ "Old Approach" Directives contained a high degree of technical details, but EU MSs would introduce national standards/regulations faster than the adoption of those directives. "New Approach" Directives are limited to essential health and safety requirements.

²⁸ CROMSOURCE, EU Recast of the Medical Device Directives: The Rocky Road to the new Medical Device Regulation, February 2014; available at: <http://www.cromsource.com/wp-content/uploads/2012/12/EU-Recast-of-the-Medical-Device-Directives.pdf>.

diagnostic medical devices)²⁹ that aim to ensure a high level of protection of human health and safety, as well as the good functioning of the Single Market³⁰. On 26 September 2012, the European Commission adopted a Proposal for a Regulation of the European Parliament and of the Council on medical devices and a Proposal for a Regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices which will, once adopted by the EP and by the Council, replace the existing three medical devices directives³¹. In addition, medical devices are implicitly targeted by the Ecodesign Directive³², as amended, which provides rules for enhancing the environmental performance of energy-related products (based on energy efficiency targets) and intends to improve free trade of these products between MSs³³. Medical devices do not explicitly appear in the list of energy-using products regulated by the Ecodesign Directive³⁴. However, in 2012 the EC acknowledged the Self-Regulatory Initiative on Eco-design for medical imaging equipment promoting the reduction of environmental impacts of medical devices³⁵.

2.1.1. Marketing authorisation process

Pharmaceuticals

Producers of medicinal products must obtain a MA before they are permitted to place a product on the EU market. The MA process may follow different procedures established by the EU (centralised, decentralised or mutual recognition procedures), or a national procedure when the application concerns only one MS. Special rules exist for the authorisation of, for instance, medicinal products for paediatric use, orphan medicinal products, traditional herbal medicinal products, vaccines and clinical trials. The present section focuses only on the general rules.

Article 8 of Directive 2001/83/EC provides that the MA application must be accompanied by, among other particulars and documents, an environmental risk assessment (ERA), as well as reasons for any precautionary and safety measures to be taken³⁶. The ERA is subject to the guideline adopted by the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA), which came into effect on 1 December 2006. However, an ERA is not required for all human pharmaceuticals. In particular, it is required for new MA applications submitted after 30 October 2005³⁷. It is important to note that

²⁹ These three main directives have been supplemented over time by several modifying and implementing directives, including the last technical revision brought about by Directive 2007/47/EC.

³⁰ See http://ec.europa.eu/health/medical-devices/regulatory-framework/index_en.htm.

³¹ See EC DG Health & Consumers' website: http://ec.europa.eu/health/medical-devices/regulatory-framework/index_en.htm. Both proposals have been debated before the Council (and the EP before that) and are currently awaiting the Council's first reading decision (procedures 2012/0266(COD) and 2012/0267(COD)). See [http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2012/0266\(COD\)](http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2012/0266(COD)) and [http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2012/0267\(COD\)](http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2012/0267(COD)) (last consulted on 8 October 2014).

³² Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of eco-design requirements for energy-related products, OJ L 285, 31.10.2009, p.10-35.

³³ See http://ec.europa.eu/enterprise/policies/sustainable-business/ecodesign/index_en.htm and <http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:32009L0125>.

³⁴ See <http://www.medical-ecodesign.com/drivers-benefits/legal-compliance>.

³⁵ European Coordination Committee of the Radiological, Electromedical and healthcare IT industry (COCIR), Self-Regulatory Initiative for medical imaging equipment, Status Report 2013, available at: http://e-health-com.eu/fileadmin/user_upload/dateien/Downloads/COCIR_SRI_Status_Report_2013.pdf.

³⁶ Directive 2001/83/EC, Article 8(3) (ca) and (g).

³⁷ It is also required for major variations and for extension applications if an increase in environmental exposure is expected, and for generics.

although an ERA is required, it results from Article 1(28) and (28a) of Directive 2001/83/EC that it is not part of the risk-benefit analysis: this risk-benefit balance is defined as an evaluation of the positive therapeutic effects of the medicinal product in relation to risks relating to the quality, safety or efficacy of the medicinal products in regards to patients' health or public health. Consequently, the ERA results have no impact on the decision to provide an authorisation.

However, when, following completion of the ERA, environmental risks cannot be excluded, risk mitigation measures (RMM) may be imposed on the applicant. Directive 2001/83/EC and its related guidelines provide for precautionary and safety measures to be taken. Such measures may consist of, for instance, an indication of potential risks presented by the medicinal product for the environment, in the documents communicated to the public (such as the package leaflet).

Medical devices

Before a medical device can be placed on the market, it is subject to a conformity assessment procedure which will depend on the classification of the device. This is a precondition to applying the European conformity (CE) mark.

The classification of medical devices is a "risk-based" system that depends on the vulnerability of the human body taking account of the potential risks associated with the devices. Classification ranges from Class I, IIa, IIb to III³⁸. It is based on the perceived risk associated with the medical device (from I as the lowest risk to III being the highest). Thus, for low-risk devices, the manufacturer is only required to make a self-declaration of conformity; for higher-risk devices and for all active implantable medical devices, conformity is assessed by a Notified Body (NB)³⁹. The NB is accredited by a MS to assess whether a medical device conforms to all applicable requirements ("essential requirements", including safety and suitability for purpose), by product testing, design review, inspections, and auditing the manufacturing processes and linked quality management systems²⁸.

The recast of the medical device regulatory framework (see above), initiated in 2008, aims notably at ensuring greater consistency (i.e. regulatory harmonisation) of regulations across the EU. Indeed, the transposition of the three medical device Directives reportedly led to differences in levels of requirements and in some cases to different approaches among Member States.²⁸ In its amendments to the draft Regulation on medical devices the EP proposed a more centralised market approval process in specific cases, in particular for class III medical devices. One proposed change in the Medical Device Regulation (as amended by the EP) is therefore the designation, by EMA, of special NBs for the conformity assessment of high risk medical devices (e.g. devices in class III), as well as the creation of a network of special NBs – to exchange good practice and ensure convergence of their work – to be established, hosted, coordinated and managed by the Commission and the Medical Device Coordination Group (MDCG), a new expert group to be set up under the revised regulation. The MDCG would have the power to review and comment on special NBs assessments of high-risk medical devices before the device is put on the market⁴⁰.

³⁸ See <http://www.mhra.gov.uk/Howweregulate/Devices/Classification/>.

³⁹ See http://www.taylorwessing.com/synapse/regulatory_medicaldevices.html.

⁴⁰ See http://www.taylorwessing.com/synapse/ti_newmedicaldevice.html.

2.1.2. Confidential business information

Pharmaceuticals

EU legislation sets out a general principle of transparency for public access to EP, Council and EC documents, which include documents drawn up but also received by them⁴¹. In the field of environment, the principle of transparency and the obligations it entails are set forth in Directive 2003/4/EC (see in particular Article 3(1)). Certain exceptions may apply to this obligation to provide access to environmental documents; such access may therefore be refused, in particular if disclosure of the information would adversely affect the confidentiality of commercial or industrial information (Article 4(2)(d)). Although these exceptions must be interpreted in a restrictive way, EMA nevertheless adopted a definition of "commercial confidential information", with regards to access to documents related to medicinal products, which appears quite broad⁴². EMA publishes a full scientific assessment report called a European Public Assessment Report (EPAR) for every medicine granted a central MA by the EC. The EPAR must notably include the reasons for EMA's opinion in favour of granting the MA, after deletion of any information of a commercially confidential nature, as well as a summary understandable to the public. In addition, Directive 2001/83/EC provides that the competent authorities must make publicly available the MA and the summary of the product characteristics (Article 21(3)), and mentions the obligation for competent authorities to draw up an assessment report, in the same terms as those of Regulation (EC) 726/2004⁴³. However, environmental data (including ecotoxicological data) and ERA results are not mentioned as having to be included in the assessment report and/or made publicly available. In practice, some EPARs contain a chapter called Eco-toxicology/Environmental Risk Assessment but, until recently, this was generally only a brief summary. Recent EPARs are however more exhaustive, providing a "summary of main study results"; some EPARs do include environmental data (endpoints). At MS level, the availability of environmental information included in the ERA varies from one State to another⁴⁴.

Medical Devices

Pursuant to the Medical Device Directives, the EU has created the European databank for medical devices (Eudamed), a web-based portal whose purpose is to strengthen market surveillance and transparency by providing MS competent authorities with fast access to information as well as to contribute to a uniform application of the Directives, in particular in relation to registration requirements. Its use is obligatory since May 2011⁴⁵. However, Eudamed is not publicly accessible.

In its amendments to the Proposal for a Regulation on medical devices, the EP intends to increase the availability of information to the public. For instance, amendment 32 proposes to add a recital to the effect that, in general, the data included in clinical investigations should not be considered commercially sensitive once the device is found compliant with regulatory requirements; however, these data would still be protected by intellectual

⁴¹ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

⁴² EMA (2006c) European Medicines Agency policy on access to documents (related to pharmaceuticals for human and veterinary use), Policy/0043, effective on 1 December 2010, Doc. Ref. EMA/110196/2006. CBI is defined as "any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information".

⁴³ Article 21(4) of Directive 2001/83/EC.

⁴⁴ BIO Intelligence Service (2013), Study on the environmental risks of medicinal products, Final Report prepared for the Executive Agency for Health and Consumers, available at: http://ec.europa.eu/health/files/environment/study_environment.pdf.

⁴⁵ See http://ec.europa.eu/health/medical-devices/market-surveillance-vigilance/eudamed/index_en.htm.

property rights with regard to the use of these data by other manufacturers. The EP also included limitations as to what should be considered “commercially sensitive information”, adding notably that “data on adverse events and safety data shall not be considered commercially sensitive information” (amendment 184 to proposed article 52(3)(b))⁴⁶.

2.2. Legislation in the US

In the US, pharmaceuticals and medical devices are governed by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended. The objective of this law is to guarantee consumers that the drugs and devices are safe and effective for their intended uses. The final regulations published in the Federal Register are collected in the Code of Federal Regulations (CFR). Section 21 of the CFR governs food and drugs in the US (including regulations of Chapter I that interpret the FD&C Act and related statutes)⁴⁷.

2.2.1. Marketing authorisation process

Pharmaceuticals

There are different types of applications for pharmaceuticals in the US, based on the type of drug involved. A distinction is thus made among: Investigational New Drug (i.e. during a new drug’s preclinical development, prior to market approval), New Drug Application (NDA), Abbreviated New Drug Application (i.e. for generics), Over-the-Counter Drugs, and Biological License Application⁴⁸. This section focuses on NDA as it is the main process for new drugs to be sold and marketed in the US.

A sponsor of a new drug who wishes to market its products must submit a NDA to the FDA. The FDA’s Center for Drug Evaluation and Research (CDER) is in charge of evaluating new pharmaceuticals before they are marketed. Before a MA is granted, the CDER assesses the application to ensure two main things: (i) that the drug works correctly and (ii) that its health benefits outweigh its known risks, based notably on data submitted by the applicant pharmaceutical company, in particular results of the tests (including laboratory and animals tests, and later clinical tests on humans) that have been carried out to prove the drug is safe and effective for its intended use⁴⁹. If the NDA is approved, the product may be marketed in the US⁴⁸.

The National Environmental Policy Act of 1969 (NEPA) requires all Federal agencies (including the FDA) to assess the environmental impacts of their actions and to ensure that the interested and affected public is informed of environmental analyses. Pursuant to section 21 CFR Part 25 (“Environmental impact considerations”), applications submitted to the FDA must include an Environmental Assessment (EA) or a claim of categorical exclusion. Indeed, EAs are required as part, among others, of certain NDAs and abbreviated applications, unless the action qualifies for categorical exclusion (for classes of actions that, as a class, do not significantly affect the quality of the human environment –

⁴⁶ See Amendments adopted by the European Parliament on 22 October 2013 on the proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 (COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)); available at: <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2013-428>.

⁴⁷ See <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm>.

⁴⁸ See <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/default.htm>.

⁴⁹ See <http://www.fda.gov/drugs/developmentapprovalprocess/>.

see 21 CFR 25.30 and 25.31)⁵⁰. If adverse environmental effects have been identified, the EA must describe measures taken to avoid or mitigate these effects. When evaluation of data or information in an EA leads to a finding that a proposed action may significantly affect the quality of the human environment, the FDA will prepare an Environmental Impact Statement (EIS) (21 CFR 25.22(b)). If an EIS is necessary, it will become available at the time of the approval of the drug; comments on the EIS may be submitted after such approval, which “can form the basis for the [FDA] to consider beginning an action to withdraw the approval of applications for a drug” (21 CFR 25.52(a) and (b)).

Medical devices

The first step to obtain FDA permission to market a medical device is its classification, which will determine the MA process to be followed. There are two separate processes for the putting on the market of medical devices: the Premarket Approval (PMA) and the Premarket Notification 510(k). These two pathways are fundamentally different. In a PMA review, FDA determines if the device is reasonably safe and effective for its intended use. It results in a type of FDA permission to market the product called “approval”. In a 510(k) review, FDA determines if the device is substantially equivalent to another legally marketed (predicate) device. The 510(k) process is unique to medical devices and results in FDA permission to market products with a “clearance” status⁵¹. These two pathways are regulated, within the FDA, by the Center for Devices and Radiological Health. The Medical Device Amendments of 1976 to the FD&C Act established three classes for medical devices, according to the potential risk it poses to a patient: Class I devices (low risk, 510(k) rarely needed), Class II (intermediate risk, 510(k) typically required) and Class III (devices supporting human life and considered of substantial importance; PMA required). If a Class III device fails to meet PMA requirements, the approval is not granted and the device cannot be marketed. The PMA process is more comprehensive, detailed, time-consuming, and expensive than the 510(k) one, in order to provide sufficient valid scientific evidence to ensure that the device is safe and effective for its intended uses⁵².

As required by 21 CFR 814.20(b)(11), an EA must be included in the PMA process for all medical devices. However, PMA status does not necessarily require an EA, or EIS, if the device is of the same type and for the same use as a previously approved device⁵³. If an EIS is necessary, it will become available at the time of the approval of the product; comments on the EIS may be submitted after such approval, which “can form the basis for the [FDA] to consider beginning an action withdraw premarket notifications or premarket approval applications for devices” (21 CFR 25.52(a) and (b)).

2.2.2. Confidential business information

Pharmaceuticals

The pharmaceutical manufacturers keep most research data as confidential commercial information or trade secret.

⁵⁰ FDA, Guidance for Industry, Environmental Assessment of Human Drug and Biologics Applications, July 1998, CMC 6, Revision 1; available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070561.pdf>.

⁵¹ See <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095308.pdf>.

⁵² Eric P. Raciti and James D. Clements, A Trap for the Wary : How Compliance with FDA Medical Device Regulations Can Jeopardize Patent Rights, IDEA-The Intellectual Property Law Review, July 2006; available at: <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=01b9a626-3ee7-4637-abdf-8dc107dc588e>.

⁵³ As specified in 21 CFR 25.34(d).

The EA will be made public by the FDA as required by regulations issued by the Council on Environmental Quality. In its Guidance document to the industry, the FDA therefore indicates that the EA should contain three distinct parts: (i) the EA summary document (non-confidential), (ii) non-confidential appendices, and (iii) appendices with confidential information used to support the EA. The EA summary document, non-confidential appendices and findings of no significant impacts are made available for public inspection to the extent allowed by applicable laws (21 CFR 25.50(a) and (b)).⁵⁰ For example, are considered confidential, and hence not publicly available: test reports, as well as environmental concentration estimates. Examples of non-confidential information include: test results physical/chemical characterisation, environmental effects tests results, and method of calculating estimates of environmental concentration⁵⁴.

Medical devices

Any report in FDA's control is subject to public disclosure in response to Freedom of Information (FOI). However, before such disclosure, FDA will delete from the report "any information that constitutes trade secret, confidential commercial or financial information" (21 CFR 803.9(b))⁵⁵.

Regarding premarket notification (510(k)) of medical devices, the FDA does not disclose publicly the existence of such a premarket notification submission for a device that is not on the market and where the intent to market the device has not been disclosed for 90 days from the date of receipt of the submission provided certain conditions are met (see 21 CFR 807.95(b)). The 510(k) submission is subject to disclosure to the public in accordance with the FOI Act, along with any data that was submitted in support of the 510(k) procedure. Manufacturers, importers and medical device facility users are required to report deaths, serious injuries and certain malfunctions to the FDA, through the Medical Device Reporting (MDR); the MDR is then publicly available on the FDA's website. However, some information is exempted from public disclosure, such as confidential commercial and financial information and trade secrets.⁵²

In the case of PMA process and pursuant to 21 CFR 814.9, the existence of a PMA file may not be disclosed by FDA before an approval order is issued unless it previously has been publicly disclosed or acknowledged. In any case, data or information contained in the file are not available for public disclosure before the order is issued. However, FDA may disclose a summary of portions of the safety and effectiveness data before an approval order or an order denying approval of the PMA issues if disclosure is relevant to public consideration of a specific pending issue. Once the FDA issues an order approving or denying approval of any PMA, it must make available to the public notably a detailed summary of information submitted to FDA respecting the safety and effectiveness of the device. The following information must be made immediately available, among others: all safety and effectiveness data and information previously disclosed to the public; any protocol for a test or study unless the protocol is shown to constitute trade secret or confidential commercial or financial information; and any adverse reaction report, product experience report, consumer complaint, and other similar data and information, after deletion of trade secret or confidential commercial or financial information. As of 30 January 1998, FDA discontinued publication of individual PMA approvals in the Federal

⁵⁴ See Attachment F in FDA, Guidance for Industry, Environmental Assessment of Human Drug and Biologics Applications, July 1998, CMC 6, Revision 1.

⁵⁵ FDA, Medical Device Reporting for Manufacturers, March 1997; available at: <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094530.pdf>. On 9 July 2013, the FDA issued a "Draft Guidance for Industry and Food and Drug Administration Staff; Medical Device Reporting for Manufacturers", which will supersede the 1997 guidance when final; available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm359130.htm>.

Register⁵⁶. The alternative adopted by the FDA is to notify the public of its decision to approve a PMA by making available, via its website, a summary of the safety and effectiveness data upon which the approval is based⁵⁷.

2.3. Main differences between the EU and US legislation

With regards to the MA of medicinal products for human use, although a centralised procedure exists at EU level, the most commonly used procedures are decentralised (through so-called decentralised procedure, as well as the mutual recognition procedure) and occur at MS level. In the US, the procedure is fully centralised with the FDA having the power to grant or deny MA for pharmaceuticals.

On both sides of the Atlantic, the pharmaceutical company must submit, as part of its application dossier, an environmental assessment - an ERA in the EU and an EA in the US which may lead to the issuance of an EIS where there may be a significant impact on quality of the human environment. In the EU, the ERA is not taken into account in the risk/benefit analysis in the decision to grant (or deny) the MA, whereas in the US, where an EIS is necessary and therefore published at the time of approval, comments on the EIS may be submitted and may be taken into account by the FDA to consider withdrawing the approval.

Not all information included in the applications submitted by pharmaceutical companies is publicly available, whether in the EU or in the US. Indeed, important data may be considered as CBI or a trade secret. In the EU, although some EPARs now include environmental data (endpoints), the legislation does not mention environmental data and ERA results as having to be included in the assessment report and/or made publicly available, whereas in the US, FDA guidance to the industry provides clear examples of what is to be considered confidential (e.g. test reports) or non-confidential information (e.g. test results).

As to medical devices, the procedure applicable to the marketing of medical devices is very different in the US and the EU. The US has a centralised system while the EU system is decentralised (with an important role devolved to NBs at MS level), although the EP, through its amendments to the EC's Proposal for a Regulation on medical devices, proposes a more centralised system for high risk medical devices. In addition, the US system is stricter than its EU counterpart. Furthermore, the US has two main pathways (PMA & 510(k)) which lead to two separate marked categories when the devices enter the market ("approval" vs "clearance"); whereas in the EU there is only one CE mark which applies to all medical devices. Approval time in the US is reported to be much longer than in the EU; consequently, in many cases manufacturers seek approval in Europe before the US⁵⁸.

Another important difference regarding medical devices is the lack of specific requirement for an ERA in the EU, whereas devices in the US are also subject to an EA and, potentially, an EIS. Comments made to an EIS may be taken into account by the FDA to consider withdrawing premarket notifications or premarket approval applications of devices.

⁵⁶ Final Rule in Federal Register Vol. 63 No. 20, Friday January 30, 1998, pg. 4571.

⁵⁷ See http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAA_papprovals/default.htm.

⁵⁸ BCG, Regulation and Access to Innovative Medical Technologies, A comparison of the FDA and EU Approval Processes and their Impact on Patients and Industry, June 2012; available at: http://www.eucomed.org/uploads/ModuleXtender/Newsroom/97/2012_bcg_report_regulation_and_access_to_innovative_medical_technologies.pdf.

Finally, some information (e.g. safety and effectiveness data and information previously disclosed to the public; any protocol for a test or study, any adverse reaction report, product experience report, consumer complaint, and other similar data and information in the PMA process) must be made publicly available by the FDA in the US, after deletion of information that constitutes trade secret or confidential commercial or financial information.

In the EU, although a databank (Eudamed) was created, the information it contains is currently not publicly available. In its report on the Proposal for a Regulation on medical devices, the EP intends to increase the availability of information to the public, provided it does not constitute commercially sensitive information.

3. COSMETICS

KEY FINDINGS

- The notification and registration of cosmetic substances and finished products on the EU market is mandatory. All substances contained in cosmetic products are subject to a strict safety assessment prior to being authorised for use in cosmetics intended to be placed on the EU market.
- In the US, manufacturers are not required to register their cosmetic establishments or their products, and no registration number is requested to import cosmetics into the US. Safety testing is not mandatory.
- Although the US legislation is not as restrictive as the EU regulation and mostly based on incentives to implement good practices, several US cosmetic manufacturers voluntarily submit their cosmetic substances and final products to safety evaluation as they are legally responsible for ensuring consumer health safety.
- Animal testing is strictly banned in the EU while US legislation allows animal testing under particular circumstances, notably as part of designs of experiments on the safety of cosmetic ingredients or final products.
- The list of prohibited substances differs between EU and US legislation (1 300 in the EU, less than 20 in the US).

Cosmetics are in direct contact with human bodies; consumers may therefore be closely affected by cosmetic ingredients and their potential impacts. Thus, providing information on the content and the appropriate use of cosmetics, as well as identifying undesirable or even hazardous effects and making the public aware of them, is an important public priority. The analysis of the cosmetic legislation in the EU and the US notably highlights the requirements for the marketing authorisation (MA) and the labelling of cosmetic products, with particular focus on safety assessment procedures. In general, the EU and the US legislation applies to cosmetics marketed in the MSs and the US respectively, whether manufactured within their territories or imported from abroad.

As of the end of the sixth round of talks, TTIP negotiations have focused on processes for regulating cosmetic ingredients (in particular UV-filters and colourants), labelling provisions, cosmetics standards/guidelines and alternatives to animal testing. The dialogue encouraged both parties to develop scientific exchanges and technical cooperation for mutual interests^{59,60}. This state of play may nevertheless have evolved following the seventh round of negotiations which ended on 3 October 2014⁶¹.

⁵⁹ See section 2.4.4 of the State of Play of TTIP negotiations after the 6th round, 29 July 2014, available at: http://trade.ec.europa.eu/doclib/docs/2014/july/tradoc_152699.pdf.

⁶⁰ EC (2013), EU-US TTIP, Technical barriers to trade, Initial EU position paper, available at: http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151627.pdf.

⁶¹ No specific information was available at the time of writing this report; see <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1154> and <http://ec.europa.eu/trade/policy/in-focus/ttip/>.

3.1. Legislation in the EU

In the EU, cosmetics are regulated under Regulation (EC) No 1223/2009⁶² which entered into force in 2013 and replaces the EU Cosmetics Directive (76/768/EEC)⁶³. In Article 2 of the Regulation, cosmetics are defined as “any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours”. The Regulation sets down several rules for, *inter alia*, placing cosmetics on the market and labelling them, which are intended to guarantee a high level of human health protection while enhancing the functioning of the internal market⁶⁴. Thus every cosmetic product is subject to free trade in the EU (within and between all MSs), but producers must ensure that all requirements are met with. The EC is supported by the Scientific Committee for Consumer Safety (SCCS)⁶⁵ in order to globally ensure the appropriate implementation of measures regarding cosmetic products within the EU.

3.1.1. Conditions for the marketing of cosmetics

Before being authorised to be placed on the EU market, cosmetics must be evidenced as safe for consumers. Since a large number of cosmetics in the EU come from a limited number of substances⁶⁶, the safety of cosmetic products relies on the safety of the substances contained in finished products. Two persons (legal or natural) are in charge of ensuring the proper application of the safety assessment procedure:

- The SCCS, delivering opinions on the safety of the substances clearly mentioned in Regulation No 1223/2009⁶⁷ (listing of substances prohibited, restricted, authorised and subject to specific requirements, respectively); and
- The “responsible person” (manufacturer, importer or distributor)⁶⁸, required to carry out a scientific and technical evaluation of all other substances of finished products that do not appear in the Regulation.

The safety assessment of cosmetic ingredients primarily consists in a risk evaluation entailing: hazard identification (resulting from *in vivo* and *in vitro* tests, clinical and epidemiological studies, among others), dose-response assessment (including determination of the No Observed Adverse Effect Level (NOAEL)), exposure assessment (taking account of quantity and frequency of exposure to the substance) and risk

⁶² Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009, p.59–209.

⁶³ Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, OJ L 262, 27.9.1976, p.169–200.

⁶⁴ See http://ec.europa.eu/consumers/consumers_safety/cosmetics/legislation/; <http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:32009R1223> and https://www.cosmeticseurope.eu/safety_and_science_cosmetic_s-europe/rules-and-regulations/the-eu-legislation.html.

⁶⁵ The SCCS provides independent scientific expertise and assesses health and safety risks of non-food consumer services and products, including cosmetics. Assessment findings are published through opinions. More information at http://ec.europa.eu/health/scientific_committees/consumer_safety/.

⁶⁶ In Article 2 of Regulation No 1223/2009, a substance is defined as “a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition”.

⁶⁷ See the lists of prohibited substances, restricted substances and authorised colourants, preservatives and UV-filters in Annexes II, III, IV, V and VI of Regulation No 1223/2009, respectively.

⁶⁸ Responsibilities and obligation of “responsible persons” are given in Articles 4 and 6 of Regulation No 1223/2009.

characterisation (considering systemic effects and margin of safety). In compliance with Regulation 1223/2009, findings of safety assessments undertaken by “responsible persons” should be made available in a Cosmetic Product Safety Report (CPSR)⁶⁹ that must be reviewed by the competent authorities of MSs. The procedure is detailed in the dedicated SCCS’ Notes of guidance for the testing of cosmetic substances and their safety evaluation⁷⁰.

As a crucial point of cosmetic safety evaluation in the EU, toxicological testing must not be conducted through animal experiments. Indeed, animal testing for cosmetic purposes (to test substances alone or in combination) is completely banned in the EU since 2009⁷¹. Consequently, every finished product or ingredient which has been subject to animal testing is not authorised on the EU market. Alternative testing measures are compulsory⁷². The EC may grant derogations under very specific conditions and provided that the SCCS expresses favourable opinion.

Once completely approved by the EC, cosmetic substances are added to the EU Cosmetic ingredients database (CosIng)⁷³. The “responsible person” is also requested to notify the resulting cosmetic products on the EU Cosmetic Products Notification Portal⁷⁴ and to keep updating the related Product Information Files as long as the cosmetics are marketed.

Marketing conditions of cosmetics are subject to changes and additional safety assessments may be required in accordance with findings from the strict market surveillance⁷⁵ (including specific and random controls) ensured by the competent authorities at MS level⁷⁶. In particular, every Serious Undesirable Effect (SUE) potentially caused by cosmetics must be immediately reported by the “responsible person” to the competent authorities of the MSs where the adverse effect appeared, following the compulsory procedure explained in the SUE Reporting Guidelines⁷⁷. In addition to corrective measures possibly implemented by the “responsible person”, the competent authorities may apply provisional measures (withdrawal, recall or restriction).

3.1.2. Labelling

The EU labelling requirements for cosmetic products aim to enhance transparency towards consumers thus reducing risks to human health (due to e.g. the presence of potential allergens and toxic substances) and to the environment (caused by e.g. polluting chemical substances possibly released into the environment when the product reaches the end of its life). Article 19 of Regulation No 1223/2009 highlights the mandatory information that must be written in visible and easily readable font with indelible ink on both containers and outer packaging of cosmetics.

⁶⁹ As specified in Annex I of Regulation No 1223/2009, the CPSR includes safety information (e.g. “toxicological profile of the substances”, “undesirable effects and serious undesirable effects”) as well as the safety assessment (with “labelled warnings and instructions of use” and “scientific reasoning”).

⁷⁰ http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_s_006.pdf.

⁷¹ Animal testing on cosmetic ingredients is forbidden since 2009, while animal testing on final cosmetic products has already been prohibited since 2004. See http://europa.eu/rapid/press-release_MEMO-13-188_en.htm.

⁷² The European Union Reference Laboratory for alternatives to animal testing develops and validates such alternative measures. More information at: http://ihcp.jrc.ec.europa.eu/our_labs/eurl-ecvam.

⁷³ <http://ec.europa.eu/consumers/cosmetics/cosing/>.

⁷⁴ See <https://webgate.ec.europa.eu/cnpn/public/tutorial.cfm?CFID=44722036&CFTOKEN=f13c636d6dbe50db-E1227A3B-0E67-604F-C93F6A147AE04C4B&jsessionid=9218f9576530a9b98aa47e3c17183043c462TR>.

⁷⁵ http://ec.europa.eu/consumers/consumers_safety/cosmetics/market_surveillance/index_en.htm.

⁷⁶ A Platform of European Market Surveillance Authorities for Cosmetics has been developed by the competent authorities to favour harmonisation of market surveillance at EU level.

⁷⁷ http://ec.europa.eu/consumers/consumers_safety/cosmetics/docs/sue_reporting_guidelines_en.pdf.

With the objective of providing information on the product content, the cosmetic labelling primarily includes the weight or volume of the product⁷⁸ and the list⁷⁹ of ingredients mentioned under the International Nomenclature of Cosmetic Ingredients in descending order of weight. Furthermore, every substance categorised as nanomaterials (NMs) has to be notified as such with "(nano)" after the chemical name. A specific Colour Index nomenclature is also required for colourants. Additional information relating to safety must be present, notably the precautions for use (partly evidenced in the CPSR) and the date of minimum durability and/or the period of time after opening⁸⁰. The labelling also contributes to cosmetic traceability through the name and address of the "responsible person", the country of origin of products imported in the EU and the batch reference number. Finally, the use of claims made on cosmetics is subject to restrictions and requires relevant scientific proof in order to prevent misleading information. According to Article 20 of Regulation No 1223/2009, ongoing cooperation between MSs would lead to harmonised criteria at EU level for using claims on cosmetics.

3.2. Legislation in the US

In the US, cosmetics are regulated under the Federal Food, Drug and Cosmetic Act (FD&C Act) and the Fair Packaging and Labelling Act (FPLA). The FD&C Act defines cosmetics by their intended use as "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap"⁸¹. Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colours, and deodorants, as well as any substance intended for use as a component of a cosmetic product. All cosmetics marketed in the country, whether manufactured there or imported from abroad, must be in compliance with the legislation.

3.2.1. Conditions for the marketing of cosmetics

According to the FD&C Act, manufacturers are not required to register their cosmetic establishments or file their product formulations with FDA, and no registration number is required to import cosmetics into the US. However, cosmetic firms are encouraged to participate in FDA's Voluntary Cosmetic Registration Program (VCRP), assisting FDA in carrying out its responsibility to regulate cosmetics. The VCRP applies only to cosmetics being sold to consumers in the US. It does not apply to cosmetics for professional use only (e.g. products used in beauty salons, spas, or skin care clinics), nor to cosmetics that are not for sale. Owners or operators of cosmetic manufacturing or packing facilities can register their establishments, using a separate Form FDA 2511 for each facility location and file a statement for each product the firm has entered into commercial distribution in the US, using a separate Form FDA 2512 for each formulation.

⁷⁸ Labelling product quantity is not compulsory for free samples, single application packs and products of less than 5ml or 5g.

⁷⁹ Contrary to other mandatory information, the list of ingredients can be written on the outer packaging only.

⁸⁰ <http://www.ceway.eu/labelling-requirements/>.

⁸¹ See Section 201 (i) of FD&C Act. In addition, whether a product is a cosmetic or a drug under the law is determined by a product's intended use. Drugs are defined as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" [FD&C Act, sec. 201(g) (1)]. Products which meet the definitions of both cosmetics and drugs must comply with the requirements for both cosmetics and drugs.

Under the FD&C Act, marketing of adulterated or misbranded products in interstate commerce is prohibited. "Adulteration" refers to violations involving product composition⁸² and "misbranding" refers to violations involving improperly labelled or deceptively packaged products⁸³. The "Draft Guidance for Industry: Cosmetic Good Manufacturing Practices"⁸⁴ provides guidance to industry and other stakeholders on FDA's current thinking concerning what constitutes Good Manufacturing Practices (GMPs) for cosmetics and how to reduce the risk of manufacturing adulterated or misbranded cosmetics⁸⁵, but no regulations set forth specific GMP requirements for cosmetics.

In accordance with the legislation, companies and individuals manufacturing or marketing cosmetics are legally responsible for ensuring the safety of their products; however, they are not requested to refer to dedicated procedures. FDA has stated that "the safety of a product can be adequately substantiated through: (a) reliance on already available toxicological test data on individual ingredients and on product formulations that are similar in composition to the particular cosmetic, and (b) performance of any additional toxicological and other tests that are appropriate in light of such existing data and information"⁸⁶. Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients.

Cosmetics are required to be safe when consumers use them according to directions in the labelling, or in the customary or expected way. Product testing is one of the things a manufacturer might do to ensure the safety of a cosmetic product. Animal testing by manufacturers seeking to market new products may be used to establish product safety if companies may determine that animal testing is necessary to assure the safety of a product or ingredient. There are no "Cruelty Free"/"Not Tested on Animals" labels specifically sanctioned by legislation, and no legal definitions for these terms⁸⁷.

Unlike other products under FDA regulations such as drugs, biologics, and medical devices, cosmetic products and ingredients do not need FDA premarket approval, with the exception of colour additives^{88,89}, but regulations prohibit or restrict the use of several ingredients in cosmetic products and require warning statements on the labels of certain

⁸² Under section 601 the FD&C Act, a cosmetic is adulterated if "it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labelling thereof, or under conditions of use as are customary and usual", "it consists in whole or in part of any filthy, putrid, or decomposed substance", "it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health" (with an exception made for coal-tar hair dyes), "its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health", or "it is, or it bears or contains, a colour additive which is unsafe within the meaning of section 721(a)".

⁸³ Under section 602 of the FD&C Act, a cosmetic is misbranded if "its labelling is false or misleading in any particular", its label does not include all required information, the required information is not adequately prominent and conspicuous, it is a colour additive, other than a hair dye, that does not conform to applicable regulations issued under section 721 of the FD&C Act, and "its packaging or labelling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970".

⁸⁴ More information at: <http://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocuments/ucm353046.htm>.

⁸⁵ This guidance updates FDA's "Cosmetic Good Manufacturing Guidelines/Inspection Checklist".

⁸⁶ In: Federal Register, March 3, 1975, page 8916.

⁸⁷ Because of that fact, some cosmetic companies promote their products with claims of this kind in their labelling or advertising.

⁸⁸ Colour additives are subject to a strict system of approval under US law (FD&C Act, sec. 721; 21 U.S.C. 379e).

⁸⁹ More information at: www.fda.gov/Cosmetics/Labeling/IngredientNames/ucm109084.htm.

types of cosmetics⁹⁰. At any time, an ingredient that has already been used in or as a cosmetic may have its safety brought into question by new information.

Section 704 of the FD&C Act authorises FDA to conduct inspections of cosmetic firms at reasonable times, in a reasonable manner, and without prior notice in order to assure compliance with the applicable laws and regulations, to determine whether cosmetics are safe and properly labelled, and to identify possible health risks and other violations of the law. During inspections, FDA may examine the following: use of prohibited ingredients, improper use of restricted ingredients, non-compliance with requirements related to colour additives, microbial contamination, failure to adhere to requirements for tamper-resistant packaging where needed, deficiencies in labelling and packaging, the adequacy of buildings and facilities, the suitability of equipment and how it is maintained, personnel training, handling of raw materials, production procedures, laboratory and other quality controls, warehousing and storage of raw materials as well as in-process and finished cosmetics, and complaint files.

3.2.2. Labelling

Proper labelling is an important aspect of putting a cosmetic product on the market. FDA regulates cosmetic labelling under the authority of both the FD&C Act and the FPLA. The required information that must appear on the principal display panel is an identity statement and an accurate statement of the net quantity of contents⁹¹. Name and place of the business, distributor statement, material facts, warning and caution statements and ingredients must appear on an information panel⁹². Regulations 21 CFR 701.2 published by the FDA offer detailed information on how to comply with the requirement for prominent and conspicuous placement of information on cosmetic labels or labelling.

3.3. Main differences between the EU and US legislation

The safety assessment procedures are fundamentally different in the EU and the US. In the EU, the “responsible person” is required to carry out a scientific and technical evaluation of all substances of finished products that do not appear in the Regulation. Its findings of safety assessments must be reviewed by MS competent authorities. In the US, cosmetic firms are legally responsible for ensuring the safety of their products and the FDA cannot require specific tests to demonstrate the safety of products or ingredients. Furthermore, the law does not require cosmetic companies to share their safety information with the FDA. The FDA is also not authorised to order recalls of cosmetics which can only be undertaken voluntarily by manufacturers or distributors.

Animal testing for cosmetic purposes is banned in the EU since 2009. Such testing is still allowed in the US under particular circumstances. The list of prohibited substances differs between EU and US legislation. In the EU more than 1,300 ingredients are banned whereas in the US less than twenty ingredients are prohibited.

In the EU, cosmetic products must be notified on the EU Cosmetic Products Notification Portal and the “responsible person” is requested to keep updating the related Product Information Files as long as the cosmetics are marketed. In contrast in the US, registration

⁹⁰ While the use of some ingredients is completely prohibited by regulations (bithionol, chlorofluorocarbon propellants, chloroform, halogenated salicylanilides, methylene chloride, vinyl chloride, zirconium-containing complexes and prohibited cattle materials), the use of other ingredients is restricted under several conditions (hexachlorophene, mercury compounds and sunscreens), as specified in [21 CFR, Parts 250.250 and 700.11 through 700.35] and [21 CFR 250.250, 21 CFR 700.13, 21 CFR 700.35] respectively.

⁹¹ As specified in Sec. 10(t), FPLA and 21 CFR 701.10.

⁹² As also specified in 21 CFR 701.2.

is not required, although cosmetic firms can voluntarily register their establishments and products.

The US regulation also applies less strict control on cosmetic labelling. For instance, contrary to the EU system, the date of minimum durability and/or the period of time after opening, as well as notification of substances categorised as NMs are not required on cosmetic packaging in the US. The use of claims made on cosmetics is not subject to restrictions and does not require relevant scientific proof in the US⁹³.

Contrary to previous regulatory differences, the US system is stricter than the EU regarding cosmetics with medicinal effects. While the EU allows the marketing of cosmetic products with certain medicinal effects, the US has extra regulatory hurdles for such products which are classified as drugs. These substances include, *inter alia*, sunscreens, anti-caries toothpaste and lip balms.

⁹³ But if the claim consists of physiological effect, the cosmetic is considered as a drug and its labelling also has to be in compliance with drugs labelling regulation.

4. FOOD AND NUTRITION

KEY FINDINGS

- The extent to which the supply chain is integrated into food traceability schemes affects the extent to which food safety risks can be prevented in different systems. The EU uses a “farm to fork” approach which includes all stages of the supply chain, including production, processing, and distribution. The US focuses on registered facilities which manufacture, process, pack, and hold food products, largely excluding the beginning and end of the supply chain.
- Due to developments under the 2011 Food Safety Modernisation Act, the US system may undergo significant changes in the near future in terms of product tracing, potentially becoming a more comprehensive traceability scheme. However other than issuing a report and recommendations to Congress based on pilot projects for a new product tracing system, the US Food and Drug Administration (FDA) has not taken any further steps to implement a new system (e.g. rulemaking).
- Based on the recommendations from the pilot projects, a US product tracing system with a standardised, uniform approach to recordkeeping would not match the EU approach which is flexible (providing an “obligation of results” rather than “obligation of means” system).
- The risk analysis for food safety differs between the US and EU. In Europe, use of the precautionary principle allows for consideration of scientific uncertainty on risks when making decisions while taking consumer opinion and economic issues into account. The US approach requires robust scientific evidence of harmful effects before taking actions that address the risks (e.g. preventive controls, recordkeeping requirements and designation of high risk foods).
- Nutrition and health claim labelling requires evaluation of the submitted evidence by both the European Food Safety Authority (EFSA) and the FDA, however while the US only considers whether there is significant scientific agreement, the EU considers science as well as stakeholder and consumer opinion before allowing products to be labelled. Structure/function labelling in the US does not require prior approval before use, but the FDA must be notified within 30 days and then not object. Function claims allowed on labels in the EU are listed and must be approved by EFSA.
- The US allows qualified health claims to be placed on food packages even if the significant scientific agreement standard cannot be met, as long as there is “credible” science to support the claim and a qualifying statement is added. The EU does not appear to have any comparable type of packaging labelling, which could be confusing and potentially misleading for consumers.

Food has been a subject of long-standing debate between the EU and US, often due to regulatory divergences and complaints by one of the parties that the other side’s measures conflict with World Trade Organization (WTO) law. For example, egg washing requirements in the US create difficulties for EU exporters; the dispute over hormone use in beef

production is one example for US exporters relating to EU requirements⁹⁴; import and planting of genetically modified organisms (GMOs) in Europe is another. The latter subject was covered in depth in the prior study, finding that the regulatory scheme for GMOs differs widely between the EU and the US in terms of risk assessment for authorisation, public consultation, public register, and labelling of food products, which are all stricter in the EU⁹⁵. The US-EU Organic Equivalency Arrangement is an example of a way in which the US and the EU have reached a mutual recognition agreement regarding each other's regulations. Thus, organic certified products from the US imported into the EU may be labelled with the EU organic label, and vice versa. Additionally, international food standards, such as the Codex Alimentarius, set general guidelines for minimum food and nutrition regulations⁹⁶.

This section analyses and compares the legal frameworks of the EU and the US relating to food and nutrition, focusing specifically on two issues: (i) traceability of food products and (ii) health claims on food labels. We explore how the different traceability systems are structured, and highlight their comprehensiveness, recordkeeping requirements, enforcement elements, and procedures for reducing food safety threats within the supply chain. The second part covering health claims on food labels explores the requirements for food labels which draw a connection between a substance found in food and a certain health component (e.g. a disease risk reduction). General divergences in ingredient labelling requirements and dietary supplement labelling will not be discussed. Additionally, food safety prevention measures are not discussed in depth.

According to the state of play following the sixth round of TTIP negotiations, the issues related to food and nutrition have not been addressed. This state of play may nevertheless have evolved following the seventh round of negotiations which ended on 3 October 2014⁹⁷.

4.1. Legislation in the EU

Legislation in the field of food and nutrition at the EU level proved necessary by past food crises or risk issues related to foodstuffs⁹⁸ (for instance Bovine Spongiform Encephalopathy – mad cow disease, food additives like aspartame, allergenic food ingredients, and the impacts of GMOs or pesticides, etc.). In the EU, the legal framework has in consequence been further developed since the beginning of the 2000s with the goal of guaranteeing food safety and hygiene along the food production chain and ensuring sufficient transparency towards consumers, and thus facilitating free trade of safe and high-quality products and protecting human health⁹⁹. Traceability

Traceability of food products appears as a key requirement of the EU's food safety policy essentially laid down in Regulation No 178/2002 on General Food Law¹⁰⁰ that entered into

⁹⁴ EU Parliament (2012) Win-win ending to the "hormone beef trade war", Press Release (settled by the EU agreeing to raise its quota for quality beef imports from the US and Canada while keeping its ban on hormone beef, in exchange for those two countries lifting their duties on certain EU products).

⁹⁵ EP (2013), Ecologic Institute and BIO Intelligence Service, Legal Implications of TTIP for the *Acquis Communautaire* in ENVI Relevant Sectors, IP/A/ENVI/ST/2013-09, PE 507.492; available at: [http://www.europarl.europa.eu/ReqData/etudes/etudes/join/2013/507492/IPOL_ENVI_ET\(2013\)507492_EN.pdf](http://www.europarl.europa.eu/ReqData/etudes/etudes/join/2013/507492/IPOL_ENVI_ET(2013)507492_EN.pdf).

⁹⁶ See <http://www.codexalimentarius.org/standards/list-of-standards/>.

⁹⁷ No specific information was available at the time of writing this report; see <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1154> and <http://ec.europa.eu/trade/policy/in-focus/ttip/>.

⁹⁸ See <http://www.efsa.europa.eu/en/efsawhat/riskassessment.htm>.

⁹⁹ See http://ec.europa.eu/food/food/foodlaw/principles/index_en.htm.

¹⁰⁰ Regulation (EC) No 178/2002 of the European Parliament and of the Council 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 OJ L 31, 1.2.2002, pp.1–24.

force on 21 February 2002, and in the “Hygiene Package¹⁰¹” – a set of regulations governing the hygiene of foodstuffs – that entered into force on 20 May 2004¹⁰², as amended.

As defined in Article 18 of Regulation No 178/2002, traceability requirements aim at tracking food and ingredients dedicated to human consumption “at all stages of production, processing and distribution” in accordance with the integrated “farm to fork” approach¹⁰³. Traceability consists of a food safety management tool, providing systems and procedures for complying with general principles of transparency and risk analysis (risk assessment, risk management and risk communication which rely on precautionary principles). From 1 January 2005, the obligation of traceability is requested from all food business operators, including importers, who must be able to identify from whom and to whom (known as individual or legal persons) products have been immediately supplied, in line with the “one-step back – one-step forward” approach. Certain sectors or categories of products (e.g. beef and fish) as well as products containing GMOs are subject to specific rules (in particular, further traceability extended to indirect suppliers and subsequent recipients excluding final retailers to consumers). In any case, product tracking has to be based on product physical flow and not only anymore on its commercial flow. In spite of the above compulsory aspects, the EU legislation remains relatively flexible since MSs food business operators are subject to an “obligation of results” rather than an “obligation of means”. Indeed, Article 18 of Regulation No 178/2002 determines goals but not the detailed ways of achieving them. Consequently, neither specific format of traceability records nor minimum duration for keeping records¹⁰⁴ is required, provided that accurate information can be made available rapidly. Guidelines established by a dedicated EU Working Group, consisting of experts from MSs designated by DG SANCO, lead operators in the implementation of traceability systems and procedures¹⁰⁵.

To date, traceability has proved an efficient mechanism for withdrawing or recalling unsafe products from the market while protecting human health and preventing unnecessary trade disruption¹⁰³.

To a larger extent, food business operators are also encouraged to implement good practices for food safety (including traceability procedures) through the “Hygiene Package”. Regulation No 852/2004 notably establishes an obligation to apply the principles of the Hazard Analysis and Critical Control Points (HACCP) system¹⁰⁶, in addition to the official controls that must be conducted by the competent authorities, as laid down in Regulation No 854/2004, as amended by Regulation No 882/2004. Among other requirements, the HACCP system decrees recordkeeping in order to prove the correct application of traceability measures and make official controls easier. In compliance with Regulation No 853/2004, establishments manufacturing food products from animal origin

¹⁰¹ Regulation (EC) 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, pp.1–54.

¹⁰² The “Hygiene Package” includes three Regulations of the EP and of the Council of 29 April 2004: Regulation (EC) No 852/2004 on the hygiene of foodstuffs, Regulation No 853/2004 laying down specific hygiene rules for food of animal origin in order to guarantee a high level of food safety and public health, Regulation No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, 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.

¹⁰³ See http://ec.europa.eu/food/food/foodlaw/traceability/index_en.htm.

¹⁰⁴ Records commonly remain available for 5 years (as done for commercial documents kept for taxation) but this duration may decrease or increase if products are perishable or not.

¹⁰⁵ See http://ec.europa.eu/food/food/foodlaw/guidance/docs/guidance_rev_8_en.pdf.

¹⁰⁶ More information at: <http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:32004R0852>.

have to give a health mark (or an identification mark) coming with specific data that contribute to products traceability¹⁰⁷.

4.1.1. Nutrition and health claims

The legal framework regulating nutrition and health claims in the EU is governed notably by Regulation (EC) No 1924/2006 on nutrition and health claims made on foods¹⁰⁸ which entered into force on 1 July 2007 and sets up different rules depending on the type of claims defined as follows¹⁰⁹:

- Nutrition claim refers to “any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to: (a) the energy (calorific value) it (i) provides; (ii) provides at a reduced or increased rate; or (iii) does not provide; and/or (b) the nutrients or other substances it (i) contains; (ii) contains in reduced or increased proportions; or (iii) does not contain”. Examples of such claims include: “low energy”, “fat-free”, “with no added sugars”, “source of fibre”, “high protein”.
- Health claim refers to “any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health”. Health claims include “function claims¹¹⁰” (e.g. “Calcium is needed for the maintenance of normal bones”), “risk reduction claims” (e.g. “Sugar-free chewing gum helps reduce tooth demineralisation [...] a risk factor in the development of dental caries”) and claims referring to children’s development (e.g. “Iron contributes to normal cognitive development of children”).

The application of Regulation No 1924/2009 has resulted in the implementation of the EU Register of Nutrition and Health Claims¹¹¹ which specifies the allowed and not-allowed claims as well as their conditions for use or the reasons for their non-authorisation, respectively. The main objective of this Register was to harmonise rules regarding claims on food labels across the EU and to enhance accuracy, clearness and consistency of such claims that must be scientifically evidenced.

While authorisations for nutrition claims are only granted for those listed in the Annex of Regulation (EC) No 1924/2006, lastly amended by Regulation (EU) No 1047/2012, authorisations for health claims depend on the targeted effects on human health. Whereas allowed “function” health claims are in a list established by the EC, health claims referring to reduction of disease risks and/or children’s development are subject to specific authorisation procedures based on individual applications¹¹². Specific application submissions are also requested for “function” health claims resulting from the latest

¹⁰⁷ See <http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:32004R0853>.

¹⁰⁸ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, OJ L 404, 30.12.2006, pp.9-25.

¹⁰⁹ Classification and definitions of claims are given in Article 2 of Regulation (EC) No 1924/2006.

¹¹⁰ In Article 13 of Regulation (EC) No 1924/2006, “function claim” describes or refers to “(a) the role of a nutrient or other substance in growth, development and the functions of the body; or (b) psychological and behavioural functions; or (c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet”.

¹¹¹ See <http://ec.europa.eu/nuhclaims/>.

¹¹² The application must include, *inter alia*, copies of available/ independent/ peer-reviewed studies conducted to prove substance benefits, and be submitted to the competent authority of a MS that informs the other MSs and the EC of the application, followed by scientific assessment and verification of the wording. For more information on the procedure, see Articles 14, 15, 16, 17 and 19 of Regulation (EC) No 1924/2006.

scientific findings or related to proprietary data¹¹³. Once in the list or once the authorisation procedure is completed, health claims can appear alone or in combination.

Assessments of scientific relevancy of health claims are carried out by the European Food Safety Authority (EFSA). In addition to EFSA's scientific advice, the EC may consider the stakeholders and consumers' opinion in particular for new "function" health claims as well as "risk reduction claims" and claims referring to children's development. The reliability of nutrition and health claims and the consumers' confidence in delivered information should be reinforced by the presence of appropriate nutrient profiles on food labels, in accordance with Article 4 of the Regulation. The scientific opinion provided by EFSA, as well as commercial and industrial analysis, allows the EC to set up comprehensive nutrient profiles that are required for the authorisation for claim labelling¹¹⁴.

4.2. Legislation in the US

Legislation in the field of food and nutrition in the US includes a network of laws and regulations at the federal, state and local level, which are administered by multiple different administrative agencies¹¹⁵. There is a general split between non-animal food products, which are regulated by the Food and Drug Administration (FDA)¹¹⁶, and animal products, governed largely by the Food Safety Inspection Service (FSIS) under the US Department of Agriculture (USDA)¹¹⁷. Due to significant annual numbers of illnesses, hospitalisations, and deaths occurring from foodborne diseases¹¹⁸, the US food safety scheme was amended by the Food Safety Modernization Act (FSMA) in 2011 with the goal to improve food safety by moving from a system of response to food contamination to prevention¹¹⁹. The FDA is in the process of implementing the legislation, e.g. issuing proposed rules, receiving and responding to comments, and finalising rules and guidance¹²⁰.

4.2.1. Traceability

Traceability of food products within US food safety policy has gradually moved from testing final products¹²¹ to the development of HACCP¹²² systems which require recordkeeping¹²³. Additionally, DNA testing and alert websites¹²⁴ have been developed and supported by the FDA, USDA, and the Center for Disease Control in order to identify the source of contamination and to enable faster responses to and containment of foodborne illness outbreaks¹²³.

¹¹³ Specific procedures apply for a request for the protection of proprietary data. See Articles 13(5), 18 and 19 of Regulation No (EC) 1924/2006.

¹¹⁴ See http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm.

¹¹⁵ See EP (2013), Keenan S and Hammond J, Food Safety Policy and Regulation in the United States, Part 2 of Public Health and Food Safety Policies and Regulation in the United States; available at http://www.europarl.europa.eu/RegData/etudes/note/join/2013/507464/IPOL_ENVI_NT%282013%29507464_EN.pdf (for an overview of various laws and agencies implementing food safety procedures in the US).

¹¹⁶ See <http://www.fda.gov/AboutFDA/WhatWeDo/History/FORqsHistory/CFSAN/ucm083863.htm>.

¹¹⁷ Federal Meat Inspection Act, 21 U.S.C. §§ 601-695; Poultry Products Inspection Act, 21 U.S.C. §§ 451-472; Egg Products Inspection Act, 21 U.S.C §§ 1031-1056.

¹¹⁸ See <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm>.

¹¹⁹ See <http://www.fda.gov/animalveterinary/products/animalfoodfeeds/ucm347941.htm>.

¹²⁰ See <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm239907.htm>.

¹²¹ General sanitation requirements under the FDA's Good Manufacturing Practice Regulation.

¹²² HACCP is a science-based approach to minimise contamination in food processing, wherein the processor identifies potential hazards that could result in unsafe food, monitors critical control points to minimise risks, and maintains records. E.g. recordkeeping under 9 C.F.R. 417.5.

¹²³ See <http://www.fda.gov/AboutFDA/WhatWeDo/History/FORqsHistory/CFSAN/ucm083863.htm>.

¹²⁴ E.g. Foodborne Diseases Activity Surveillance Network (FoodNet).

However, the US food safety system has been criticised for lacking a preventive approach, instead regulating the response to food safety problems after they have already occurred¹²⁵. Thus, the 2011 FSMA includes new requirements for hazard analysis and risk-based preventive controls by registered facilities^{126,127}, as well as development of new regulations for on-farm produce safety by the FDA¹²⁸. The FSMA also contains a provision for “Enhanced Tracking and Tracing of Food and Recordkeeping”¹²⁹. This complements FDA’s new enforcement authority to detain food and issue mandatory recalls of products, as well as suspend facilities’ registration¹³⁰.

Under FSMA, pilot projects were carried out in order to inform the development of a new product tracing system by the FDA and USDA¹³¹. Two pilot projects tested mock trace-back / trace-forward procedures within multi-actor, diverse supply chains¹³². Ten recommendations were made for the development of the product tracing system, including: recordkeeping should be uniform for all risk categories of food, food tracing plans should be required of all members of the food supply chain, recorded data and its submission should be more standardised, and products should be traceable farther backwards and forwards than just the preceding supplier and the receiving entity¹³³. However, other than compiling a report to Congress on the pilot projects and these recommendations, FDA has taken no further action (e.g. rulemaking).

The FSMA also requires the FDA to create science-based recordkeeping requirements for high risk foods to help trace those products, but the identification of high risk foods is still in process¹³⁴. This includes retailers needing to know from which farms their products were sourced, while farms do not have to keep records of their direct sales but may be required to provide information if an outbreak occurs and it is traced back to their farm. Finally, FSIS has developed stricter traceability regulations for beef. Establishments which produce and supply source materials for “raw ground beef products and bench trim products” will

¹²⁵ The European Consumer Organisation (BEUC) (2014), Food and the Transatlantic Trade & Investment Partnership (TTIP), http://www.beuc.org/publications/beuc_x_2014_030_ipa_beuc_position_paper_ttip_food_0.pdf (contrasting the US system with the EU “farm to fork” approach).

¹²⁶ 21 U.S.C. §350d (“any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States”, including foreign facilities importing into the US; excluding farms and retail food establishments (e.g. restaurants)).

¹²⁷ These are “risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis conducted under subsection (b) and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis”. *Ibid*.

¹²⁸ 21 U.S.C. §350h; see <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm#Imports>.

¹²⁹ 21 U.S.C. §2223.

¹³⁰ 21 U.S.C. §350i.

¹³¹ 21 U.S.C. §2223(a).

¹³² McEntire, J. and Bhatt, T. (2012) Pilot Projects for Improving Product Tracing along the Food Supply System – Final Report. Report by the Institute of Food Technologists. Despite inconsistencies in data submission, many of the pilot project participants had tools and processes in place to be able to provide timely data. However, the projects were opt-in, so the participating industries and actors “were likely forward-leaning and not necessarily representative of the average with respect to their product tracing practices”.

¹³³ McEntire, J. and Bhatt, T. (2012) Pilot Projects for Improving Product Tracing along the Food Supply System – Final Report. Report by the Institute of Food Technologists.

¹³⁴ 21 U.S.C. §2223(d) A draft methodological approach to identifying high risk foods was published in the Federal Register calling for comments and scientific evidence. 79 F.R. 16800, Notice by FDA: Designation of High-Risk Foods for Tracing and for Scientific Data and Information; Extension of Comment Period.

be subject to new faster trace-back and recall procedures upon presumptive positive findings of *E. coli* O157:H7 beginning 14 October 2014¹³⁵.

4.2.2. Nutrition and health claims

US food labelling predominantly stems from the 1990 Nutrition Labelling and Education Act¹³⁶, the 1997 Food and Drug Administration Modernization Act¹³⁷, and the Dietary Supplement Health and Education Act of 1994.¹³⁷ Food labels may display different types of claims about the product, including nutrient content, structure/function and health claims. Nutrient content claims relate to the level of a nutrient in a product, such as “high in fibre” or “low in sodium”. They must be authorised by FDA if there is any implication that the product is better than others due to the nutrient level, for example, meeting the regulatory standards for “low sodium” as opposed to a label which simply states “200 mg of sodium”¹³⁸. Structure/function claims relate to an ingredient’s effect on the structure or function of the body, such as “calcium builds strong bones”; or a nutrient deficiency disease which the food product may benefit, such as scurvy, though these latter claims must have an accompanying statement of how widespread the disease is in the US.¹³⁸ Structure/function claims are not preapproved by FDA before labelling is allowed – the manufacturer must have evidence the claim is truthful and not misleading and submit a notification of the claim text to FDA within 30 days of marketing a product with the claim. Health claims are defined as “any claim made on the label or in labelling of a food, including a dietary supplement, that expressly or by implication, including ‘third party’ references, written statements (e.g. a brand name including a term such as ‘heart’), symbols (e.g. a heart symbol), or vignettes, characterises the relationship of any substance to a disease or heart-related condition”.¹³⁸

For example, an FDA authorised health claim is “Three grams of soluble fibre from oatmeal daily in a diet low in saturated fat and cholesterol may reduce the risk of heart disease. This cereal has 2 grams per serving”¹³⁹. Health claims tie a substance in the food to a reduction in the risk of a disease, but not to the cure, mitigation, or treatment of a disease. They are subject to premarket review and authorisation by FDA.

There are three ways in which a health claim may legitimately appear on a food label.

- The FDA may specifically authorise a health claim after either receiving a health claim petition from the firm wishing to place the label on its product or initiating its own evaluation of the scientific evidence available to support the claim, referred to as an evidence-based review system¹⁴⁰. Publicly available data, studies, and written information about the substance/disease relationship are evaluated¹⁴¹. The information may be submitted by the private firm or found through FDA’s literature search. The standard for approval is “significant scientific agreement”. Basically, qualified experts would need to find the claims plausible on the basis of a

¹³⁵ 79 F.R. 47417, 13 August 2014 (Notices) Presumptive positive findings are based on tests indicating an establishment’s beef materials are *E. coli* O157:H7 positive but before official confirmation has been received, which can take up to 8 days. 77 F.R. 26725.

¹³⁶ 21 U.S.C. §343(r).

¹³⁷ Amending the FD&C Act, 21 U.S.C. §§ 301 et seq.

¹³⁸ See <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/%20ucm064908.htm>.

¹³⁹ 21 C.F.R. part 101.14.

¹⁴⁰ FDA (2009) Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims – Final, available at: <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073332.htm>.

¹⁴¹ *Ibid.* (e.g. studies are reviewed for their methodological quality, quantity of evidence, replication of study results, relevance to the US population, and consistency of evidence supporting the claim).

sufficient body of available scientific information with consistent results; full scientific consensus is not required¹⁴⁰.

- New health claims may also be used after submitting a notification to the FDA about an “authoritative statement” made by an official scientific body (National Academy of Sciences or US Government)¹⁴². If the FDA does not object within 120 days, the notifying firm and other product developers may use the health claim¹³⁶.
- Qualified health claims are based on emerging scientific evidence that there may be a link between the substance and a risk reduction for a disease or a health-related condition, but there is not enough evidence to meet the significant scientific agreement standard. Thus, no authorising regulation may be issued by FDA. If it is found that “credible evidence” exists as to the claim, however, the FDA may issue a letter¹⁴³ specifying how the qualified health claim may be used (i.e. with a qualifying statement to show that the proposed health claim is limited)¹⁴⁴.

4.3. Main differences between the EU and US legislation

The major difference between US and EU traceability systems is the extent to which the entire supply chain is monitored, recorded, and able to give trace-back and trace-forward information. In the EU, the “farm to fork” approach includes all stages of food production from manufacturing and processing to distribution. In the US monitoring focuses on “registered facilities” in the manufacturing and processing part of the supply chain with the aim of preventing and intercepting contaminated food. One of the objectives of the FSMA is to increase the risk-based preventive controls of registered facilities, but these do not include farms or retail facilities. Thus, the ends of the supply chain are largely excluded (with the notable exception of on-farm produce safety standards). However, the FDA’s pilot projects testing methods for a new product tracing system indicate that the US system may move toward a more comprehensive tracking system like that in the EU, with specific traceability standards implemented all the way from the farm through the supply chain.

In terms of the standard for risk regulation (assessing risks, managing risks, and communicating risks), the EU continues to follow the precautionary principle that takes account of scientific uncertainty to implement measures addressing risks. Other factors (e.g. economic costs and benefits and consumer opinion) are also considered when making risk-related decisions¹⁴⁵. This differs from the US approach which strictly relies on science-based assessments to prove risks and consequently take regulatory actions¹²⁵.

In terms of recordkeeping, the EU is flexible in its recordkeeping requirement. The system is structured as one of “obligation of results” rather than “obligation of means”; thus, it is more focused on goals than on how food business operators must achieve them. The recommendations for future development of a US product tracing system based on the

¹⁴² Saldanha, L.G. (2008) US FDA Regulations Governing Label Claims for Food Products, Including Probiotics, *Clinical Infectious Diseases* 46: 119-21 (excluding dietary supplements).

¹⁴³ Within its enforcement discretion.

¹⁴⁴ See <http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm111447.htm>; an example of a qualified health claims is “Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [] gram of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.]”, FDA (2004) Omega-3 Fatty Acids & Coronary Heart Disease. Docket No. 2003Q-0401 Enforcement discretion letter.

<http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073992.htm#omega3>.

¹⁴⁵ See http://ec.europa.eu/food/food/foodlaw/principles/index_en.htm; and http://europa.eu/legislation_summaries/food_safety/veterinary_checks_and_food_hygiene/f80501_en.htm.

pilot projects called for more standardisation of data and submission of data, uniform recordkeeping for all risk categories of food, and food tracing plans to be completed by all members of the supply chain. These results suggest that the US system may develop more rigid requirements that may not align well with the EU's flexible approach to recordkeeping.

Nutrition (nutrient content in the US system) and health claim labels on food packaging require specific authorisation under both the US and EU systems. These claims pose a potential risk of misleading consumers if they are not verified since they connect a substance in the food to a better nutrition or health benefit. The scientific evidence needed for health claims under the different systems varies. The EU requires independent, peer-reviewed studies for the assessment of the health claim carried out by the EFSA. In the US, the FDA also conducts an evidence-based review, but the private firm petitioning for the health claim may submit non-independent studies for consideration. The FDA screens all the evidence and concludes whether there is significant scientific agreement about the health claim. In the EU, in addition to the EFSA scientific assessment, the EC may consider stakeholders' and consumers' opinions when reviewing whether to allow health claims. Thus, it is possible that regulatory decisions on health claims in the EU might be based on factors in addition to the science. The US system allows structure/function claims to be used without prior approval if the firm can substantiate the claim and submits a notification to the FDA within 30 days of first marketing a product with the claim. This ability to market a product with a claim on the label prior to approval by the regulatory body is not available in the EU. Finally, qualified health claims appear to be unique to the US system. A lower standard of scientific agreement ("credible evidence") about the food substance and disease risk reduction connection is accepted, but a qualifying statement acknowledging the weaker state of scientific support for the claim must be added.

5. SANITARY AND PHYTO-SANITARY MEASURES

KEY FINDINGS

- An important part of the approval process of plant protection products (PPPs) for marketing and use in both the EU and US is the assessment of potential impacts on the environment, animal and human health. Economic costs and benefits of the use of PPPs are also taken into account in the US.
- The renewal of marketing authorisation procedures is more frequent in the EU (every 10 years) than in the US (every 15 years).
- Numerous risk mitigation measures are carried out on both sides to prevent adverse effects, however the approach taken differs, including reliance on the precautionary principle in the EU, which allows for consideration of scientific uncertainty regarding risks when making a decision, and on robust scientific evidence of harmful effects in the US before taking actions that address the risks.
- While the US legislation is primarily based on the 2000 Plant Protection Act and the 2002 Animal Health Protection Act, the EC is currently conducting a reform of the EU legal framework which should enter into force in 2016 through the Animal and Plant Health Package.

Sanitary and phyto-sanitary (SPS) issues cover any matter of food safety and animal and plant health, including the consideration of ecological and environmental conditions. SPS measures refer to any measures aiming to protect human or animal or plant life or health from risks related for instance to contaminants in foods and beverages, the spread of pests and organisms carrying or causing disease, as well as measures minimising such risks. The development of harmonised worldwide SPS measures is based on the Agreement on the application of SPS measures¹⁴⁶ that was set up by the World Trade Organization (WTO) in 1994. All WTO Members, among which the EU and US, must fulfil this Agreement that lays down an international framework for the application of SPS measures, in particular: the scientific assessment of risks, the determination of the relevant level of SPS protection, the procedures of approval and control, the requirements for SPS products importation. As far as appropriate, WTO Members should implement SPS measures on the basis of existing guidance established by, notably, the Codex Alimentarius Commission¹⁴⁷, the World Organization for Animal Health¹⁴⁸, and the International Plant Protection Convention (IPPC)¹⁴⁹. In general, SPS measures should be applied "only to the extent necessary to protect human, animal or plant life or health" and should not be used as "an excuse for protecting domestic producers from competition".¹⁴⁶ Stricter SPS measures may be applicable in some WTO Members' territories provided that scientific evidence or risk assessment findings support them. In case of insufficient

¹⁴⁶ For further information, see http://www.wto.org/english/docs_e/legal_e/15-sps.pdf.

¹⁴⁷ The Codex Alimentarius Commission was established by FAO and WHO in 1963 to protect consumer's health and ensure fair trade of food products through international food standards. See <http://www.codexalimentarius.org/>.

¹⁴⁸ The World Organization for Animal Health has replaced the Office International des Epizooties (OIE, created in 1924) since 2003, endorsing the same global mission of improving animal health. See <http://www.oie.int/en/>.

¹⁴⁹ The IPPC was approved by the 6th FAO Conference in 1951 with the goal of protecting wild and cultivated plants by limiting pest introduction or spread. See <https://www.ippc.int/>.

scientific references at international level, WTO Members are required to temporarily adopt the precautionary principle¹⁵⁰.

The analysis and comparison of legal frameworks regulating SPS measures in the EU and the US will focus more particularly on (i) the marketing authorisation (MA) procedures for the use of plant protection products (PPPs), and (ii) the risk mitigation measures (RMMs) of environmental and health impacts due to inadequate use of PPPs or unsuitable practices for animal health and welfare. This chapter does not, however, address veterinary medicinal products.

At the sixth round of TTIP negotiations, the EU and the US agreed on pursuing the reflection on SPS measures through considering “the institutional architecture, equivalence, audits and verification, and trade facilitation” and revisiting existing SPS measures “in a collaborative manner” and “with the level of protection that each side deems appropriate” for risk assessment and management¹⁵¹, as first-mentioned in the EC’s initial position paper¹⁵². This state of play may nevertheless have evolved following the seventh round of negotiations which ended on 3 October 2014¹⁵³.

5.1. Legislation in the EU

The EU regulates SPS impacts and more specifically PPPs through a number of Directives and Regulations. The resulting European guidelines and implementation rules for plant protection, animal health and food safety are mostly administrated by the Health and Consumers Directorate-General (DG SANCO) of the EC.

5.1.1. Marketing authorisation procedures

In the EU, the legislation about MA of PPPs is governed by Regulation (EC) No 1107/2009 on the placing of PPPs on the market¹⁵⁴, as amended. Since PPPs are “products consisting of or containing active substances”, the scope of the Regulation refers to PPPs and to their active substances¹⁵⁵.

Before being introduced in a product that potentially reaches the market, every active component is subject to an EC assessment based on strict criteria (efficacy, relevance of metabolites, composition, method of analysis, impact on human health and the environment, ecotoxicology, residues) that prove its favourable effect on plant production. The assessment must also ensure environmental and animal health protection as well as negligible levels of exposure to humans (the following active substances are hence not authorised: endocrine disrupters, persistent or bio-accumulative organic pollutants, substances classified as category 1A or 1B Carcinogenic, Mutagenic or Toxic for reproduction).¹⁵⁶ In practical terms, the producer of an active substance is required to submit an application for EU approval to a Rapporteur MS which carries out a preliminary

¹⁵⁰ See paragraph 7 of Article 5 of the Agreement on the application of SPS measures, http://www.wto.org/english/tratop_e/sps_e/sps_issues_e.htm.

¹⁵¹ See EC, State of play of TTIP negotiations after the 6th round, 29 July 2014; available at: http://trade.ec.europa.eu/doclib/docs/2014/july/tradoc_152699.pdf.

¹⁵² EC (2013), EU-US TTIP, Sanitary and phyto-sanitary issues, Initial EU position paper; available at: http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151625.pdf.

¹⁵³ No specific information was available at the time of writing this report; see <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1154> and <http://ec.europa.eu/trade/policy/in-focus/ttip/>.

¹⁵⁴ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309, 24.11.2009, p. 1–50.

¹⁵⁵ Pursuant to Article 2 of Regulation (EC) No 1107/2009, active substances are “substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products”.

scientific and technical evaluation and draws up a Draft Assessment Report. This report is then reviewed by the EC and the European Food Safety Authority (EFSA), which, after public and expert consultation, may approve the active substance for a maximum of 10 years. Beyond this duration, renewal of approval must be submitted under several restrictive conditions (category of users, intended crop, substance purity)^{156,157}.

Afterwards, MSs are responsible for the MA of the PPPs (containing the components previously approved by the EC) on their territory in compliance with EU requirements. The competent authorities generally have up to 12 months to assess a MA application¹⁵⁸ (assessment of the possible impacts of the PPPs on the environment, animal and human health taking account of specific conditions in the regions of interest) and deliver their conclusions. In case of an admissible application, the MA validity lasts 10 years but the authorities are entitled to amend or withdraw the MA before it expires and should be renewed (for instance, when a PPP no longer complies with one of the criteria for MA, or following the occurrence of an adverse effect potentially related to PPP use that endangers the environment or human or animal health). If a product contains an active substance that has not been authorised by the EC yet, MSs may grant a provisional MA valid for 3 years. The Regulation also lays down requirements for the product classification, labelling and packaging, and for the official controls conducted by MSs and audited by the EC^{156,157}.

The active substances authorised within the EU are listed in the EU Pesticides Database¹⁵⁹.

5.1.2. Risk mitigation measures

Regarding plant protection, RMMs have been established in accordance with Council Directive 2000/29/EC on protective measures against the introduction and spread of plant pests within MSs¹⁶⁰, as amended¹⁶¹. The Directive notably sets up requirements for plant and plant product import into the EU or into Protected Zones in the EU¹⁶², in compliance with the EU list of regulated pests that are banned from introduction and spread in the whole or part of MSs¹⁶³. In addition to the management strategies for plant pest and disease risks, DG SANCO has developed a notification system for plant health interceptions, known as EUROPHYT¹⁶⁴.

With respect to PPPs (including pesticides) more specifically, three EU reference documents came into force in 2009 with the objective of promoting sustainable use of pesticides to ensure limited risks and impacts of pesticide use on the environment and

¹⁵⁶ See <http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:32009R1107>.

¹⁵⁷ See http://ec.europa.eu/food/plant/pesticides/index_en.htm.

¹⁵⁸ The initial examination period may be extended by 6 months if some information proving the benefits of the product is missing in the application dossier.

¹⁵⁹ The EU Pesticides Database is available at: http://ec.europa.eu/sanco_pesticides/public/?event=homepage.

¹⁶⁰ Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plant or plant products and against their spread with the Community, OJ L 169, 10.7.2000, pp.1-185.

¹⁶¹ Numerous emergency measures complete Plant Health Directive 2000/29/EC, including, for instance, Emergency measures against *Phytophthora ramorum* (Commission Decision 2002/757/EC as amended) or against Potato spindle tuber viroid (Commission Decision 2007/410/EC). Emergency measures are available at: http://ec.europa.eu/food/plant/plant_health_biosafety/legislation/emergency_control_measures_en.htm.

¹⁶² The EU plant health import requirements are included in Annexes III and IV of Directive 2000/29/EC.

¹⁶³ The EU list of regulated pests is included in Annexes I and II of Directive 2000/29/EC.

¹⁶⁴ Information on EUROPHYT at: http://ec.europa.eu/food/plant/plant_health_biosafety/europhyt/index_en.htm

human health: Directive 2009/128/EC on the sustainable use of pesticides¹⁶⁵, Directive 2009/127/EC on machinery for pesticide application¹⁶⁶ and Regulation (EC) No 1185/2009 on statistics on pesticides placed on the market and used¹⁶⁷. In particular, Directive 2009/128/EC requires MSs to adopt the precautionary principle to assess pesticide use consistency and to implement a National Action Plan (with quantitative objectives, timetables, risk-monitoring indicators, guidelines for Integrated Pest Management (IPM) and alternative techniques). Training programmes and certifications for professional users, distributors and advisors are also required by the Directive. In addition, the competent authorities of MSs shall inspect pesticide application equipment once every 5 years (the control frequency will be reduced to once every 3 years from 2020) and may grant derogations to the prohibition of pesticide aerial spraying¹⁶⁸.

The legal framework of RMMs for animal health protection is mainly based on the proposal for a Regulation on Animal Health¹⁶⁹ adopted by the EC in 2013 (expected to enter into force in 2016, along with the global Animal and Plant health Package¹⁷⁰), as part of the Animal Health Strategy 2007-2013 "Prevention is better than cure"¹⁷¹. The Regulation proposal would clearly determine farms and veterinaries' responsibilities in preventing and eradicating animal diseases, promote the use of new technologies (dedicated to pathogen surveillance and electronic registration of animals), reinforce the detection and control of diseases (among which emerging diseases due to climate change). Furthermore, RMMs for animal welfare protection must be consistent with the EU Animal Welfare Strategy 2012-2015¹⁷². The related EU legislation applies not only on the farm¹⁷³, but also during transport¹⁷⁴ and at time of slaughter or killing¹⁷⁵.

Since 2013, the EC has carried out a reform of the legal framework governing RMMs for plant production and animal health and welfare, in order to make it clearer and more based on a risk approach and to harmonise procedures at EU level. The resulting proposal forms part of a wider Animal and Plant Health Package¹⁷⁰ to strengthen the enforcement of

¹⁶⁵ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides, OJ L 309, 24.11.2009, pp.71-86.

¹⁶⁶ Directive 2009/127/EC of the European Parliament and of the Council of 21 October 2009 amending Directive 2006/42/EC with regards to machinery for pesticide application, OJ L 310, 25.11.2009, pp.29-33.

¹⁶⁷ Regulation (EC) No 1185/2009 of the European Parliament and of the Council of 25 November 2009 concerning statistics on pesticides, OJ L 324, 10.12.2009, pp.1-22.

¹⁶⁸ See <http://eur-lex.europa.eu/legal-content/EN/LSU/?uri=CELEX:32009L0128>. The proposal for a Regulation on Animal Health (and other proposals constituting the Animal and Plant Health Package) is awaiting Council first reading position and the EP has voted it first reading position (procedure 2013/0136(COD) on animal health). See [http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2013/0136\(COD\)&l=en](http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2013/0136(COD)&l=en) (last consulted on 8 October 2014).

¹⁶⁹ EC, Proposal for a Regulation of the European Parliament and of the Council on Animal Health, COM(2013) 260 final (adopted on 6 May 2013 and based on 400 individual acts); available at: http://ec.europa.eu/food/animal/docs/ah-law-proposal_en.pdf.

¹⁷⁰ See http://ec.europa.eu/dgs/health_consumer/pressroom/animal-plant-health_en.htm.

¹⁷¹ See http://ec.europa.eu/food/animal/diseases/strategy/docs/animal_health_strategy_en.pdf.

¹⁷² See http://ec.europa.eu/food/animal/welfare/index_en.htm.

¹⁷³ Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes, OJ L 221, 08.08.1998, pp.23-27.

¹⁷⁴ Council Regulation (EC) No 1/2005 of 22 December 2004, on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC, and Regulation (EC) No 1255/97, OJ L 3, 5.1.2005, pp.1-44.

¹⁷⁵ Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing, OJ L 340, 31.12.1993, pp.21-34.

safety standards for the whole agri-food chain, which in turn is supported by the animal and plant health programme 2014-2020 (new financial framework)¹⁷⁶.

5.2. Legislation in the US

SPS measures in the US are included in many different pieces of legislation and implementing regulations. Furthermore, the regulatory authority to issue rules and guidance, inspect, remove, revoke, and destroy various threats to food safety and animal, plant, and human health is spread across multiple administrative bodies as well¹⁷⁷.

5.2.1. Marketing authorisation procedures

The SPS measures regulating PPPs in the US primarily stem from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetics Act (FD&C Act). The Food Quality Protection Act of 1996 (FQPA) amended these laws to establish new, higher standards for authorisation of pesticides by the US Environmental Protection Agency (EPA), the administrative body primarily responsible for pesticide regulation¹⁷⁸.

In order to be distributed, transferred or sold in the US, a pesticide must be registered by EPA according to the process outlined in FIFRA¹⁷⁹. In general, this process is aimed at preventing “unreasonable adverse effects to the environment” and harm to human, flora and fauna health¹⁸⁰. As this standard is defined, determination of whether a pesticide is too harmful (or “unreasonable”) includes consideration of environmental, social and economic costs and benefits of its use¹⁸¹. Thus, the more beneficial a pesticide is economically, the more adverse effects it would be possible for it to have on the environment and human health yet still receive approval.

The applying entity must submit certain information to the EPA in order to register a new active ingredient to be used in pesticides, a new product for an existing pesticide, or a new use for a registered product¹⁸². The evaluation includes an extensive scientific review, for which the applicant must submit data regarding the potential environmental fate of the pesticide, dietary and non-dietary hazards to humans, and hazards to domestic animals and non-target organisms from the pesticide’s use¹⁸³. Risk assessments are developed by the EPA to evaluate the potential for aggregate, cumulative (from different pesticides with similar effects), and occupational harm to humans, animals, and plants, as well as the risk of contamination of surface and groundwater due to leaching and run-off.

¹⁷⁶ See http://ec.europa.eu/food/animal/diseases/index_en.htm.

¹⁷⁷ E.g. the USDA agencies (the Animal and Plant Health Inspection Service (APHIS) and FSIS), FDA and EPA – For an overview of these agencies in relation to SPS measures, see Froman, M. (2014) 2014 Report on Sanitary and Phyto-sanitary Measures. Report by the United States Trade Representative.

¹⁷⁸ See <http://www.epa.gov/pesticides/regulating/>.

¹⁷⁹ 7 U.S.C. § 136a; Pesticides are defined as substances or mixtures that are intended to prevent, destroy, repel or mitigate pests; to act as plant regulators; or to be a nitrogen stabiliser. See <http://www2.epa.gov/pesticide-registration/about-pesticide-registration>.

¹⁸⁰ *Ibid.* “Unreasonable adverse effects to the environment” standard defined as “(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under Section 408 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 346a)”.

¹⁸¹ FIFRA, 7 U.S.C. § 136. <http://www.epa.gov/agriculture/lfra.html#Registration%20of%20New%20Pesticides>.

¹⁸² See <http://www2.epa.gov/pesticide-registration/about-pesticide-registration> (Submission includes the pesticide’s ingredients, the crops and sites on which a certain amount will be applied, the timing and frequency of use, and the storage and disposal procedures).

¹⁸³ 40 C.F.R. part 158; <http://www.epa.gov/agriculture/lfra.html#Registration%20of%20New%20Pesticides>.

The registration safety standard used to determine tolerances for pesticides which will be used on food or feed was also amended by the FQPA. The scientific analysis determines whether there is a “reasonable certainty of no harm” in terms of aggregate exposure¹⁸⁴. This is a science-based standard, so economic benefits are not considered. The aggregate exposure analysis includes dietary residues (on foods as well as in drinking water) as well as other reliable exposure information¹⁸⁵. However, the EPA has been criticised for not considering the combined effect of exposure to multiple different types of pesticides, particularly their inert as well as active ingredients, which may be worse than their effect in isolation (the “cocktail effect”)¹⁸⁶. Data submitted by applicants for all types of pesticide registration must be from studies which meet the EPA’s testing guidelines¹⁸⁷. Additionally, there is (limited) public participation in the pesticide registration process after the information has been analysed, the risk assessments drafted, and a proposed decision issued¹⁸⁸.

Pesticides containing new, unregistered active ingredients may temporarily receive conditional registration and be used before the EPA issues a final decision, but only if it determines that the pesticide “will not cause any unreasonable adverse effect on the environment” while the registrant generates and submits the required data, and will be in the public interest¹⁸⁹. The US system is hence relatively inclined to accept a certain level of risk. Additionally, the registration process for pesticides with new active ingredients intended for minor uses only (such as for small-scale use in fruit and vegetable production) was streamlined by the FQPA¹⁹⁰.

An important part of the pesticide registration is product labelling; legal use of the pesticide must match the label requirements, which is the standard of use that must result in no unreasonable harm to the environment¹⁹¹.

5.2.2. Risk mitigation measures

RMMs within the US legislative and regulatory landscape are also widespread in terms of SPS measures. Plant and animal protection from pests and disease threats as well as plant and animal health promotion are predominantly based on the 2000 Plant Protection Act and the 2002 Animal Health Protection Act¹⁹². The Animal and Plant Health Inspection Service (APHIS) is the primary agency working to prevent the introduction of foreign pests and diseases into US agriculture¹⁹³.

¹⁸⁴ Federal Food, Drug and Cosmetic Act, section 408(b) (2) (A) (ii), as amended.

¹⁸⁵ EPA, Pesticide Registration (PR) Notice 97-1: Agency Actions under the Requirements of the Food Quality Protection Act, January 31, 1997 (e.g. non-occupational exposure and heightened risk standards for children and infants).

¹⁸⁶ See e.g. http://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/FAQ_on_pesticides.pdf.

¹⁸⁷ See <http://www2.epa.gov/pesticide-registration/about-pesticide-registration>.

¹⁸⁸ See <http://www2.epa.gov/pesticide-registration/public-participation-process-registration-actions>.

¹⁸⁹ 7 U.S.C. § 136a (7); <http://nationalaglawcenter.org/overview/pesticides/>. The National Resources Defense Council in the US argues that the conditional registration serves as a loophole to let under-tested pesticides on the market and endangers public health. Sass, J. and Wu, M. (2013) Superficial Safeguards: Most Pesticides are Approved by Flawed EPA Process.

¹⁹⁰ Minor uses are defined as “pesticides for which the total United States production for a crop is fewer than 300,000 acres, or whose uses do not provide sufficient economic incentive for a registrant to support initial or continuing registrations”.

¹⁹¹ See <http://www2.epa.gov/regulatory-information-topic/pesticides#label>.

¹⁹² See http://www.aphis.usda.gov/wps/portal/banner/aboutaphis?1dmy&urile=wcm%3apath%3a%2Faphis_cont_library%2Fsa_about_aphis%2Fsa_overview%2Fct_history.

¹⁹³ The responsibility for preventative inspections of animal and plant imports carried out at US ports was transferred in large part from the APHIS Plant Protection and Quarantine division to the newly-formed Department of Homeland Security’s Customs and Border Protection in 2002. *Ibid*.

The Plant Protection and Quarantine division under APHIS regulates import of plants and plant products into the US¹⁹⁴. In general, plant pests and, *inter alia*, plants, plant products and noxious weeds are or may be restricted from importation and movement between the states (unless authorised by permit)¹⁹⁵. The regulations based on robust scientific assessment called for under the Plant Protection Act have been developed using transparent and accessible processes, which detail protocols for importation and categories for treatment of the import (e.g. quarantined, Not Authorised Pending Pest Risk Analysis, experimental, therapeutic, etc.)¹⁹⁶. A phyto-sanitary certificate of inspection completed by the exporting country authority must accompany imported materials for propagation¹⁹⁷. Additionally, the APHIS Plant Pest and Disease Management and Disaster Prevention Programs were expanded under the 2014 Farm Bill, which strengthens mitigation, inspection, and risk analysis to protect US agriculture from foreign pests and diseases¹⁹⁸.

The legislative framework for animal health in the US is the Animal Health Protection Act, which consolidated all of the prior laws regarding animal quarantine, rules for import, transport of animals between states, inspections, and seizures¹⁹⁹. The Veterinary Services division of APHIS implements the animal health system, conducting *inter alia* the National Animal Health Surveillance System and coordinating a nationwide network of centres for improved animal health monitoring and risk analysis²⁰⁰. Monitoring of imported animals' health at the border is a key responsibility, which can be divided between live animals and animal materials, both of which need to have a permit for legal importation²⁰¹. Additionally, RMMs exist for animal welfare in the US in terms of the Animal Welfare Act of 1966, as amended²⁰². In addition to regulating the transportation, sale, and handling of animals by research facilities, pet stores, and at auction sales, veterinary certification is required in order to prevent the spread of diseases²⁰³.

Finally, with respect to PPPs, the FQPA mitigates risk to both the environment and human health through the measures for reauthorisation. Existing tolerances for food residue are reviewed every 10 years to determine whether their toxicity and environmental impacts necessitate revocation of the registration²⁰⁴. Pesticide registrations are reviewed every 15 years, which involves public notice and comment on the available scientific information, the EPA's draft risk assessments regarding human health and environmental risks, and the proposed registration decisions²⁰⁵. An important issue under development in the US is the

¹⁹⁴ See http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/planthealth?1dmy&urile=wcm%3apath%3a%2FAPHIS_Content_Library%2FSA_Our_Focus%2FSA_Plant_Health%2FSA_Import%2F.

¹⁹⁵ 7 U.S.C. §§ 7111-12.

¹⁹⁶ 7 U.S.C. § 7111; 7 C.F.R. part 319; See http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/planthealth?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_our_focus%2Fsa_plant_health%2Fsa_import%2Fsa_permits%2Fsa_plant_products%2Fsa_plants_for_planting%2Fct_q37.

¹⁹⁷ APHIS-USDA, APHIS' Plant Inspection Stations: Protecting American Agriculture from Foreign Pests and Diseases, Program Aid No. 1942.

¹⁹⁸ See http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/planthealth?1dmy&urile=wcm%3apath%3a%2Faphis_content_library%2Fsa_our_focus%2Fsa_plant_health%2Fsa_domestic_pests_and_diseases%2Fsa_farm_bill%2Fct_farm_bill.

¹⁹⁹ 7 U.S.C. §§ 8301-22.

²⁰⁰ http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalhealth?1dmy&urile=wcm%3apath%3a%2FAPHIS_Content_Library%2FSA_Our_Focus%2FSA_Animal_Health%2FSA_Program_Overview%2F.

²⁰¹ http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalhealth?1dmy&urile=wcm%3apath%3a%2FAPHIS_Content_Library%2FSA_Our_Focus%2FSA_Animal_Health%2FSA_Import_into_US%2F.

²⁰² 7 U.S.C. §§ 2131-59.

²⁰³ 7 U.S.C. § 2143.

²⁰⁴ See http://www.epa.gov/pesticides/regulating/laws/fqpa/fqpa_implementation.htm#usda (this has "resulted in the revocation or modification of almost 4,000 food tolerances").

²⁰⁵ See <http://www2.epa.gov/pesticide-reevaluation/opportunities-participate-pesticide-reevaluation>.

Endocrine Disruptor Screening Program, for which EPA must gather information and assess whether pesticide substances have hormonal effects on humans. EPA is in the process of developing the screening and testing requirements, but most chemicals have not been analysed yet due to insufficient scientific data since the monitoring and demonstration science is new and not validated²⁰⁶. Training and support through the EPA's IPM programs (e.g. the Pesticide Environmental Stewardship Program) and grants also aim to reduce the environmental impacts from pesticide use through voluntary uptake of IPM techniques²⁰⁷. Part of the EPA's compliance monitoring for FIFRA includes assuring good laboratory quality and integrity of the data submitted to it; inspecting pesticide manufacturers, retailers, applicators, and farms; protecting workers from negative effects of occupational exposure; registering manufacturers and monitoring output; as well as monitoring imports and exports of pesticides²⁰⁸.

5.3. Main differences between the EU and US legislation

Under EU legislation, MA for PPPs primarily depends on the level of protection of the environment and animal health and the degree of exposure to human health risks, while the US legislation also considers the economic profitability of the products prior to being placed on the market (through an economic, social, and environmental costs and benefits analysis of PPP use).

Both the EU and US regulations require a scientific assessment and a registration submission for the use of PPPs, however the EU expects independent laboratory studies whereas US companies are allowed to submit their own studies to demonstrate they meet the standard²⁰⁹. Another difference is that the application of SPS rules in the EU involves two levels of responsible entity (the EU level, through the EC with the support of the EFSA, and the MS level, through competent authorities) while the EPA is the main body responsible for SPS rule application in the US.

An additional difference relating to the approval of PPPs is the MA validity period for the use of PPPs which is longer in the US than in the EU. The evaluation of risks potentially related to active substances contained in PPPs must be renewed every 15 years in the US versus every 10 years in the EU, although tolerance findings for food and feed residues in the US have to be reviewed every 10 years. The EU risk assessment includes the determination of the maximum residue level of PPPs in food and feed, which is hence reviewed every 10 years. In the US, the evaluation of tolerance for residues in food and feed is also conducted every 10 years but in a dedicated procedure separately from the risk assessment. PPPs consisting of new active ingredients are temporarily authorised for 3 years on the EU market and until the EPA's final decision in the US. This difference demonstrates the tendency in the US system to be willing to accept a certain degree of risk and thus to allow use of PPPs and then revoke it if significant adverse impacts are found, rather than the EU approach postponing approval in the face of environmental or human health risk despite lack of scientific certainty.

The approach for implementing RMMs also differs between the EU and the US since it basically rests on the precautionary principle (including uncertainty assessment) in the EU and, by contrast, on accurate scientific-proved findings in the US. However, preventing the introduction and spreading of foreign pests and diseases is at the core of legislation in both

²⁰⁶ See <http://www.epa.gov/endo/pubs/edspoverview/background.htm> and <http://corporateeurope.org/international-trade/2014/07/ttip-lose-lose-deal-food-and-farming>.

²⁰⁷ See <http://www.epa.gov/pestwise/index.html>; and <http://www.epa.gov/pesp/grants/regionalaggrants.html>.

²⁰⁸ See <http://www.epa.gov/compliance/monitoring/programs/fifra/index.html> (Note: federal standards for protecting workers from health impacts from exposure are currently under debate as being insufficient).

²⁰⁹ See <http://corporateeurope.org/international-trade/2014/07/ttip-lose-lose-deal-food-and-farming>.

the EU and US. Furthermore, the EU legislation notably insists on the sustainable use of pesticides to limit adverse effects on the environment and human health.

Finally, the US legal framework governing animal health protection has already been reorganised (with the consolidated Animal Health Protection Act) contrary to the EU legislation which is still under reform through the development of a global Animal and Plant Health Package.

6. NANOMATERIALS

KEY FINDINGS

- In both the EU and the US, the legislation for the use and declaration of nanomaterials (NMs) or products containing NMs is implicitly considered in general regulations on chemicals, namely the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) in the EU and Toxic Substances Control Act (TSCA) in the US.
- Some EU product-specific legislation explicitly includes requirements for NMs. This is the case for NMs contained in cosmetics, food additives and biocides which are subject to notification and labelling rules. This is not the case in the US.
- A commonly agreed definition of NMs and dedicated legislation for NMs are under development on either side of the Atlantic, with ongoing public consultations, workshops, research programmes, etc.

Nanomaterials (NMs) refer to substances with dimensions measured in billionths of a metre, or nanometres (nm). Two categories of NMs are mainly produced and used in the world: metal-based NMs²¹⁰ and carbon-based NMs²¹¹. Due to their various physical (e.g. size, shape and solubility) and chemical (e.g. structural or molecular formula and charge tension) parameters of interest, NMs have specific properties and thus high potential for many applications in different fields including medicine (e.g. tumour therapies), cosmetics (e.g. UV-filters in sun creams), food (e.g. synthetic amorphous silica as anticoagulant in food powders), vehicles (e.g. carbon black in tyres, lithium-ion batteries for electrical cars), energy (e.g. solar panels) and textiles (e.g. anti-odours)^{212,213}. In both the EU and the US, there is currently no legal framework which explicitly lays down specific rules for NMs. Ongoing consultations and workshops conducted on both sides should lead to a common definition of NMs agreed at international level and to legislation specifically dedicated to NMs in the EU and the US. Such developments require consideration of the increasing technical and scientific progress on NMs and would ensure better transparency, safety and market surveillance. This section hence focuses on NMs as far as possible (and not on chemical substances as a whole), with particular attention to the developing legislation and choices being considered in the EU and the US with respect to registration and labelling of NMs.

The issue of NMs has not been addressed during the sixth round of TTIP negotiations; this may have changed following the seventh round of negotiations which ended on 3 October 2014²¹⁴.

6.1. Legislation in the EU

As provided by Commission Recommendation No 2011/696/EU²¹⁵, NMs are defined in the EU as “natural, incidental or manufactured material containing particles, in an unbound

²¹⁰ Examples of NMs constituted of metals: ZnO, TiO₂, SiO₂, CuO, CeO₂, Al₂O₃, Fe₂O₃, etc. for metal oxides, and Ag, Au, Fe, Pt, ZnS, CdS, CdSe, etc. for metals.

²¹¹ Examples of NMs constituted of carbon: carbon nanotubes and fullerene C₆₀.

²¹² EC, Nanotechnology as a policy issue; see http://ec.europa.eu/research/industrial_technologies/policy_en.html.

²¹³ EC, EU nanotechnology strategy; see http://ec.europa.eu/health/nanotechnology/policy/index_en.htm.

²¹⁴ No specific information was available at the time of writing this report; see <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1154> and <http://ec.europa.eu/trade/policy/in-focus/ttip/>.

state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm". In some cases where warranted by concerns for the environment, health, safety or competitiveness, the number size distribution share can be adjusted. At the present time, there is no dedicated legislation for the use and declaration of NMs or products containing NMs at the EU level²¹⁶. The general legal framework that implicitly regulates NMs in the EU is Regulation (EC) No 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)²¹⁷ that came into force in 2007 and sets down requirements for chemical substances among which NMs, and Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging (CLP)²¹⁸ of dangerous substances and mixtures. The use of NMs for particular applications may be subject to specific legislation such as in the fields of cosmetics (Regulation (EC) No 1223/2009 on cosmetics products), food safety (Regulation (EC) No 133/2008 on food additives and Regulation (EU) No 1169/2011 on Food Information to Consumers) and biocides (Regulation (EU) No 528/2012 on biocide products)²¹⁹.

In compliance with REACH, the registration of NMs manufactured or imported at 1 tonne or more is required. Registration dossiers must include all relevant information on NMs (properties, uses, effects, exposure, classification and labelling) and are submitted to the European Chemicals Authority (ECHA). At volume of 10 or more tonnes per year, a chemical safety report based on a chemical safety assessment (with, *inter alia*, toxicity testing) has to be included in the registration dossier. Dossiers are often unclear in whether and how they address "substances at the nanoscale"²²⁰, notably because the tick box "nanomaterial" is on a voluntary basis. Registrants are required to update information, especially regarding risks to human health or the environment²¹⁹. REACH also requires suppliers of a chemical substance to provide all parties along the supply chain (including the users) with information on the properties of the substance²²¹. According to the CLP Regulation, NMs that fulfil criteria for classification as hazardous (depending on the forms of physical states in which the NMs are used in the products placed on the market) must be notified to ECHA, classified and labelled appropriately, without thresholds of tonnage of manufactured or imported NMs²²².

²¹⁵ Commission Recommendation of 18 October 2011 on the definition of NMs, OJ L 275, 20.10.2011, pp.38-40.

²¹⁶ See http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/index_en.htm.

²¹⁷ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration evaluation, authorisation and restriction of chemicals, establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commissions Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/105/EC and 2000/21/EC, OJ L 136, 29.5.2007, pp.3-280.

²¹⁸ Regulation (EC) 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 (EC) No 1907/2006.

²¹⁹ Validation workshop on transparency measures for NMs, 30 June 2014, Brussels – Presentation: "Introduction to the EU legislative framework for NMs & the study on transparency measures for NMs, M.J. Prinz (DG ENTR); available at: http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index_en.htm#h2-2.

²²⁰ The term "substance at the nanoscale" was used in the Commission Staff Working Paper on Regulatory aspects of NMs in the context of REACH.

²²¹ EP (2013), Ecologic Institute and BIO Intelligence Service, Legal Implications of TTIP for the *Acquis Communautaire* in ENVI Relevant Sectors, IP/A/ENVI/ST/2013-09, PE 507.492; available at: [http://www.europarl.europa.eu/RegData/etudes/etudes/join/2013/507492/IPOL_ENVI_ET\(2013\)507492_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/etudes/join/2013/507492/IPOL_ENVI_ET(2013)507492_EN.pdf)

²²² EC, Annex II: final version of "Classification, Labelling and Packaging of NMs in REACH and CLP". Doc CA/90/2009.

Regarding product-specific legislation, cosmetics containing NMs must be notified by the “responsible person”²²³ to the EC 6 months before being placed on the market (providing chemical and physical characteristics, estimated quantity of NMs in the cosmetic, toxicological profile, safety data and expected exposure conditions). The Scientific Committee on Consumer Safety (SCCS) may be requested by the EC to provide its opinion on the safety of NMs use for cosmetic purposes²²⁴. Under the EU Cosmetics Regulation, the list of cosmetic ingredients must also specify the presence of NMs with “(nano)” after the name of the chemical substance. Similar labelling requirements apply for food containing NMs²¹⁹.

At EU level, the EC Directorates-General that are cooperating in drawing up an explicit legal framework for NMs include DG Enterprise and Industry (ENTR)²¹⁶, DG SANCO²¹³ and DG Research and Innovation (RTD)²¹². The development of the legislation is based on an “integrated, safe and responsible approach”²¹³ and should rely on a continuous review and adaptation of rules in the light of further improvements and findings from stakeholders’ dialogue. Risk assessment of NMs would be at the core of the future EU legislation on NMs (appropriate evaluation methods and expected results before marketing authorisation) and should be carried out on a case-by-case basis. EU Scientific and Advisory Committees as well as independent risk assessors would be consulted to analyse potential risks due to specific nanoparticles properties or specific uses²¹².

A Consultation on the modification of the REACH Annexes on NMs²²⁵ was undertaken by the EC in 2013 to enhance health and environmental protection through clarifying the way NMs are addressed and safety demonstrated in the registration dossiers. In addition, a Consultation on transparency measures for NMs on the market²²⁶ was launched by the EC in 2014 to elaborate on the most relevant means to ensure higher transparency and regulatory oversight on NMs. This Consultation is part of the impact assessment that follows on the Communication on the Second Regulatory Review on NMs sent by the EC in 2012²²⁷. A Study to support the Impact Assessment of relevant regulatory options for NMs in the framework of REACH was conducted in 2014²²⁸, and a validation workshop²²⁹ took place in Brussels gathering numerous stakeholders (e.g. consumers and industry associations, trade unions, business support organisations, competent authorities) to discuss first findings of this Study. Potential EU Registry and Observatory of NMs or products containing NMs are thus under consideration²¹⁶.

At national level, several MSs have conducted initiatives to enable the registration of NMs in both raw material form and final consumer products, according to either voluntary or

²²³ Responsibilities and obligation of “responsible persons” are given in Articles 4 and 6 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ L 342, 22.12.2009, pp.59–209.

²²⁴ While EC authorisation has been granted for the use of titanium oxide as nanoscale mineral UV-filters in sun creams after SCCS positive opinion of December 2007 (which requested an additional impact assessment actively followed up by EC), the EC did not authorise the use of zinc oxide as nanoscale UV-filter due to unfavourable opinion of the SCCS in 2003 (insufficient data to ensure product safety). More general SCCS opinion on safety of NMs in cosmetics available at: http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf.

²²⁵ See http://ec.europa.eu/environment/consultations/nanomaterials_2013_en.htm.

²²⁶ See http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/public-consultation_en.htm.

²²⁷ Communication from the Commission to the European Parliament, the Council and the European and Social Committee on the Second Regulatory Review on NMs, COM/2012/0572 final.

²²⁸ Matrix Insight Ltd (2014), A Study to support the Impact Assessment of relevant regulatory options for nanomaterials in the framework of REACH, Final Report FC ENTR/2008/006, lot 3; available at <http://ec.europa.eu/DocsRoom/documents/5826/attachments/1/translations/en/renditions/native>.

²²⁹ EC (DG ENTR), Validation workshop on transparency measures for nanomaterials, 30 June 2014, Brussels; See http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index_en.htm#h2-2.

mandatory reporting schemes. In particular, France has set up a trial in 2012-2013 to register NMs produced, used or imported within its territory for quantities higher than 100 g/yr. Data is gathered in the Nano-R database²³⁰. The mandatory annual Declaration of Nanomaterials aims to gain knowledge about NMs, to enhance their traceability and to gather available information about risks assessments of NMs for communication to public²³¹. Other countries (like Belgium and Denmark) are setting up or considering setting up mandatory reporting procedures²³².

6.2. Legislation in the US

In the US, many NMs are considered as "chemical substances"²³³ and thus regulated by legislation on materials and chemicals under the Toxic Substances Control Act (TSCA). Playing a leading role in this field, the EPA has changed its approach to the regulation of NMs. Having previously sought to encourage NM manufacturers to voluntarily provide information through the Nanoscale Materials Stewardship Program (NMSP)²³⁴, EPA is shifting toward mandatory approaches, both to gather information and to impose standards on the manufacture, use, and disposal of NMs. To ensure that NMs are manufactured and used in a manner that protects against unreasonable risks to human health and the environment, EPA is pursuing a comprehensive regulatory approach under TSCA. This four-step approach includes: (i) a pre-manufacture notice (PMN), (ii) a significant new use rule (SNUR), (iii) an information gathering rule, and (iv) a test rule.

Regarding the NM registration process in particular, TSCA requires manufacturers of new chemical substances to provide specific information²³⁵ to the Agency for review prior to manufacturing chemicals or introducing them into commerce (PMN). Section 5 of TSCA requires anyone who plans to manufacture or import a new chemical substance for a non-exempt commercial purpose²³⁶ to provide EPA with notice before initiating the activity. This PMN must be submitted at least 90 days prior to the manufacture of the chemical²³⁷. EPA can take action to ensure that those chemicals that pose an unreasonable risk to human health or the environment are effectively controlled, including limiting the uses of the NMs, requiring the use of personal protective equipment, limiting environmental releases, and requiring testing to generate health and environmental effects data. Manufacturers are encouraged to contact EPA if they need assistance determining whether

²³⁰ See <https://www.r-nano.fr/>.

²³¹ Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES), *Éléments issus des déclarations des substances à l'état nanoparticulaire*, November 2013; available at: http://www.developpement-durable.gouv.fr/IMG/Rapport_public_format_final_20131125.pdf.

²³² JRC Science and Policy Reports (2014), *Consideration on information needs for nanomaterials in consumers products – Discussion of a labelling and reporting scheme for nanomaterials in consumers products in the EU*; available at: http://ihcp.jrc.ec.europa.eu/our_activities/nanotechnology/traceability-report.

²³³ Under TSCA, the term "chemical substance" means any organic or inorganic substance of a particular molecular identity, including any combination of these substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any element or uncombined radical. Chemicals substances on the Inventory include: organics, inorganics, polymers, and UVCBs (chemical substances of unknown or variable composition, complex reaction products, and biological materials). The Inventory, nor TSCA, covers chemical substances subject to other US statutes, such as foods and food additives, pesticides, drugs, cosmetics, tobacco, nuclear material, or munitions.

²³⁴ In 2007, EPA launched the NMSP which was centred on voluntary industry efforts and research and included a basic programme for reporting available information as well as a more in-depth programme to develop data, including testing, over a longer time frame. The Program concluded in 2009 and an interim report is available at: epa.gov/oppt/nano/nmsp-interim-report-final.pdf. No final report has been issued since then.

²³⁵ The information required includes all available data regarding chemical identity, production volume, by-products, use, environmental releases, disposal practices, and human exposure.

²³⁶ More information available at: www.epa.gov/oppt/newchemicals/pubs/pmnchart.htm.

²³⁷ More information available at: www.epa.gov/oppt/newchemicals/index.htm.

their NMs are subject to new chemical notification requirements²³⁸. In 2010, EPA issued technical guidance for assessing and screening level risks for and exposure to NMs²³⁹.

EPA has permitted limited manufacturing of new chemical NMs through the use of Consent Orders²⁴⁰ and SNURs under TSCA. The Agency has developed a SNUR under section 5(a)(2) of TSCA to ensure that NMs receive appropriate regulatory review²⁴¹. The SNUR would require persons who intend to manufacture, import, or process new NMs based on chemical substances listed on the TSCA Inventory²⁴² to submit a Significant New Use Notice (SNUN)²⁴³ to EPA at least 90 days before commencing that activity. The SNUNs would provide the Agency with a basic set of information on NMs, such as chemical identification, material characterisation, physical/chemical properties, commercial uses, production volume, exposure and fate data, and toxicity data. This information would help the Agency to evaluate the intended uses of these NMs and to take action to prohibit or limit activities that may present an unreasonable risk to human health or the environment. However, it is not always authorised to share this information with the public since the EPA is required, under section 14 of TSCA, to keep a large amount of information about chemicals confidential²⁴⁴.

EPA is developing an Information Gathering Rule under TSCA section 8(a)²⁴⁵ to require the submission of additional information to ensure a more comprehensive understanding of NMs that are already in commerce. Under TSCA Section 4, EPA is proposing a rule to require testing for certain NMs that are already in commerce. EPA would be particularly interested in classes of NMs not already being tested by other federal and international organisations.

Currently, the US does not have general labelling requirements for NMs. The US Food and Drug Administration has not issued explicit guidance on the disclosure of NMs use in

²³⁸ Since 2005, EPA has received and reviewed over 100 new chemical notices under TSCA for nanoscale materials.

²³⁹ EPA, Interim Technical Guidance for Assessing Screening Level Environmental Fate and Transport of, and General Population, Consumer, and Environmental Exposure to Nanomaterials, 17 June 2010; available at www.epa.gov/oppt/exposure/pubs/nanomaterial.pdf.

²⁴⁰ "One outcome of EPA's review of a PMN for a new chemical substance is the issuance of an order under section 5(e) of the TSCA. Most TSCA section 5(e) orders issued by EPA are Consent Orders that are negotiated with the submitter of the PMN. When reviewing a PMN for a new chemical substance, the Agency can determine that use under certain specific conditions and with appropriate precautions would not pose an unreasonable risk, but that use under other conditions may pose an unreasonable risk. TSCA section 5(e) Consent Orders are only binding on the original PMN submitter for that substance. Consequently, after issuing a section 5(e) Consent Order, EPA generally promulgates a SNUR that mimics the Consent Order to bind all other manufacturers and processors to the terms and conditions contained in the Consent Order." More information available at: <http://www.epa.gov/opptintr/newchems/pubs/cnosnurs.htm>.

²⁴¹ The SNUR would identify existing uses of nanoscale materials based on information submitted under the Agency's voluntary Nanoscale Materials Stewardship Program and other information.

²⁴² See www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/howto.html.

²⁴³ Under section 5(a) of TSCA and 40 CFR part 721, if EPA promulgates a SNUR, a manufacturer or processor wishing to engage in a designated SNUN has to notify EPA at least 90 days before engaging in the new use. In many cases, EPA will need to respond to a SNUN by amending the SNUR to allow companies other than the SNUN submitter (such as the submitter's processor customers) to engage in the newly approved use(s).

²⁴⁴ EP (2013), Ecologic Institute and BIO Intelligence Service, Legal Implications of TTIP for the *Acquis Communautaire* in ENVI Relevant Sectors, IP/A/ENVI/ST/2013-09, PE 507.492; available at: [http://www.europarl.europa.eu/RegData/etudes/etudes/JOIN/2013/507492/IPOL_ENVI_ET\(2013\)507492_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/etudes/JOIN/2013/507492/IPOL_ENVI_ET(2013)507492_EN.pdf).

²⁴⁵ TSCA Section 8(a) gives EPA the broad authority to require, by rulemaking, manufacturers (includes importers) and processors of chemical substances to maintain records and/or report such data as EPA may reasonably require to carry out the TSCA mandates.

labelling for any product category. In its Nanotechnology Task Force report²⁴⁶, published in 2007, disclosure of NM use on a case-by-case basis was recommended.

6.3. Main differences between the EU and US legislation

Currently, the use of NMs is regulated by legislation on materials and chemicals under REACH in the EU and TSCA in the US, which have significantly different approaches. REACH is much more stringent than TSCA. According to REACH, all chemicals on the EU market must be registered with the ECHA, which includes the submission of safety data, whereas, according to TSCA, the submission of safety data is required in particular cases and chemicals authorised on the market before 1976 can remain on the market without any testing or registration requirements. In addition, fewer restrictions on chemicals (conditions of use or ban) are imposed in the US where a large amount of information on chemicals may be kept confidential. Although there is no obligation in the US or at EU level for the registration of NMs, some EU MSs have already implemented NM registration rules within their own territory.

Furthermore, there are currently no NM labelling policies in the US while several EU regulations require the labelling of NMs contained in specific products, in particular cosmetics and food.

In the EU and the US, specific legislation dedicated to NMs is still under development. On both sides, the ongoing development of legislation includes some monitoring programmes and risk assessments of NM uses, as well as several research projects that tend towards increasing funding. Further understanding and knowledge on potential health and environmental impacts of exposure to NMs are still required, as well as methods to estimate exposure and identify risks. In addition to explicit rules for NMs, a definition of NM should be agreed at international level to enhance the dialogue between stakeholders from different countries or sectors and thus the harmonisation of legislation related to NMs.

²⁴⁶ FDA, Nanotechnology Task Force Report 2007, 23 July 2007; available at: www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/UCM2006659.htm.

7. CLONING

KEY FINDINGS

- In the EU, food from cloned animals falls under the Novel Food Regulation (NFR), requiring food products from cloned animals to undergo pre-market approval, based on a safety risk assessment, and be subject to specific labelling requirements. To date, no requests for approval under the NFR for food products derived from cloned animals have been submitted. These provisions do not extend to food from the offspring of cloned animals.
- In 2013, the EC tabled legislation covering prohibitions on animal cloning, the marketing of animal clones and ensuring that food from cloned animals is not placed on the EU market. The EU's proposed new legislation on cloning would prohibit imports of products from cloned animals, but not imports of the more commercially relevant products from the progeny of cloned animals.
- In the US, there are no binding regulations for animal cloning or for marketing or labelling of cloned animal products. In 2008, the US Food and Drug Administration completed a comprehensive multi-year assessment of cloning risks and determined that meat and milk from cow, pig, and goat clones and the offspring of any animal clones are as safe as food from conventionally-bred animals and that no further regulation or labelling requirements are needed. However, industry has been requested to continue to follow a voluntary moratorium against putting cloned animal products on the market.
- The lack of US monitoring and labelling of cloned animal products could create serious difficulties for oversight of imports of these products to the EU.

Cloning is a technology of asexual reproduction producing near exact genetic copies of the organism cloned, i.e. without modification of genes. The main purposes for which cloning is undertaken are reproductive cloning, i.e. cloning with the aim of increasing the population of certain species, and therapeutic cloning used for medical purposes.

So far, researchers have cloned a wide range of biological materials, including genes, cells, and for different types of animals, including animals used in agriculture such as sheep, goats, and horses. Currently, animal cloning is taking place, for example, in Australia, Argentina, Brazil, Canada, Japan and the US²⁴⁷. However, it is estimated that it will take many years before products from cloned animals could be commercially marketed, in light of the costs of cloning involved. So far, only products from animals cloned for other purposes than commercial ones would be available for sale, but this is considered "economically unattractive and thus rather unlikely" by the EC²⁴⁸. Rather, it would be

²⁴⁷ EC, FAQ: Commission tables proposals on animal cloning and novel food, 18 December 2013; available at http://europa.eu/rapid/press-release_MEMO-13-1170_en.htm.

²⁴⁸ See EC, Commission Staff Working Document, Executive summary of the impact assessment accompanying the document proposal for a Directive of the European Parliament and of the Council on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes, and Proposal for a Council Directive on the placing on the market of food from animal clones, 18 December 2013, SWD(2013) 520 final, p. 2; available at: http://ec.europa.eu/food/food/biotechnology/novelfood/documents/cloning_executive_summary_en.pdf.

products from the progeny of cloned animals that would be marketed²⁴⁹. In other words, if a cow is cloned, it is not the cloned cow whose milk or meat may be marketed, but rather the meat and milks of the off-spring of the cloned cow.

Cloning is a controversial technology that has provoked many ethical debates, in particular when it comes to cloning humans or entire animals²⁵⁰. Other concerns relate to animal welfare, the impact of cloning on biodiversity, and human health.

Concern has been expressed that TTIP could allow for US cloned meat to be imported to the EU without restriction or labelling²⁵¹. The latest overview on the state of negotiations on cloning published by the EC does not indicate that the issue of cloning has been touched upon in the negotiations so far²⁵².

This analysis focuses on the regulation of the marketing of products from cloned animals as well as the labelling of such products in the EU and the US.

According to the state of play following the sixth round of TTIP negotiations, the issues of cloning have not been addressed. This state of play may nevertheless have evolved following the seventh round of negotiations which ended on 3 October 2014²⁵³.

7.1. Legislation in the EU

Within the EU, food from cloned animals currently comes within the purview of the Novel Food Regulation (NFR)²⁵⁴. This regulation covers all food not consumed to a "significant degree" before May 1997, i.e. before the regulation entered into force. Under the regulation, food products from cloned animals are subject to pre-market approval, based on a safety risk assessment²⁵⁵. This requirement applies to both domestic and imported products. No request for approval for food products derived from cloned animals has ever been submitted under the NFR²⁵⁶. By implication, no such products can currently be legally marketed within the EU, whether produced within the EU or imported (e.g. from the US).

In addition, specific labelling requirements that are additional to labelling requirements applicable to all food stuffs would apply to such products. Consumers must be informed about the composition, nutritional value, or effects, or intended use of a novel food or its components, if the novel food or food ingredient is not equivalent to an existing one²⁵⁷.

²⁴⁹ Wiemer, Maria. EU Risk Governance of 'Cloned Food': Regulatory Uncertainty between Trade and Non-Trade. In *Balancing Between Trade and Risk: Integrating Legal and Social Science Perspectives*, edited by M. B. A. van Asselt, Esther Versluis, and Ellen Vos, 33–57, Routledge, 2013, p.51.

²⁵⁰ For example, in a 2008 Eurobarometer survey 61% of the EU citizens responding supported the statement that "animal cloning was morally wrong", see European Commission, Flash Eurobarometer No 238, Analytical Report, 2008, p. 5; available at: http://ec.europa.eu/public_opinion/flash/fl_238_en.pdf.

²⁵¹ See e.g. EP, Questions for written answer to the Commission. Rule 117, 28 March 2014; available at: <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+WQ+E-2014-003933+0+DOC+XML+V0//EN>; BEUC, "Food and the Transatlantic Trade & Investment Partnership (TTIP)", 5 July 2014; available at: http://www.beuc.org/publications/beuc-x-2014-030_ipa_beuc_position_paper_ttip_food_0.pdf.

²⁵² See EC, State of play of TTIP negotiations after the 6th round, 29 July 2014; available at: http://trade.ec.europa.eu/doclib/docs/2014/july/tradoc_152699.pdf.

²⁵³ No specific information was available at the time of writing this report; see <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1154> and <http://ec.europa.eu/trade/policy/in-focus/ttip/>.

²⁵⁴ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ L 43, 14.2.1997, p. 1–6.

²⁵⁵ Articles 4 - 7 of the Novel Food Regulation.

²⁵⁶ Proposal for a Council Directive on the placing on the market of food from animal clones, COM(2013) 893, p.3; available at: http://ec.europa.eu/food/food/biotechnology/novelfood/documents/cloning-2013-0433_app_en.pdf.

²⁵⁷ Article 8 (1) of the Novel Food Regulation.

The requirements of the NFR do not extend to food derived from the offspring of cloned animals²⁵⁸. This has given rise to concerns that such food products could be imported to the EU from other countries and without indicating their mode of production on labels.

In 2008, the EP called upon the EC to propose legislation that would prohibit (i) the cloning of animals, (ii) the farming of cloned animals or their offspring, (iii) the placing on the market of meat or dairy products derived from cloned animals or their offspring, and (iv) the importing of cloned animals, their offspring, semen and embryos from cloned animals or their offspring, and meat or dairy products derived from cloned animals or their offspring²⁵⁹. In 2009, inter-institutional discussions on cloning started in the context of the negotiations on a proposal streamlining the approval process of the 1997 NFR. No agreement could be reached between MSs and the EP. A major issue of contention was how to deal with products from the offspring of cloned animals²⁶⁰. Subsequently, the EP called upon the EC to present a proposal on cloning based on an impact assessment.

EFSA has published various statements and opinions on animal cloning²⁶¹.

In 2013, the EC tabled a proposal for specific legislation relating to cloning, a Directive of the EP and the Council on the cloning of animals of bovine, porcine, ovine, caprine, and equine species kept and reproduced for farming purposes²⁶² and a Council Directive on the placing on the market of food from clones.²⁵⁶ According to the first proposal, all MSs would be required to prohibit animal cloning and the placing on the market of animal clones and embryo clones. The ban is justified by reference to concerns for the welfare of animals produced by cloning which were raised by the European Food Safety Agency; the expectation is expressed in the document that the technology will become better, more sophisticated over time and its effect clearer. The second proposal requires MSs to ensure that food from cloned animals is not placed on the EU market; this includes measure to prevent imports of such. The rationale given by the EC for these measures is consumer perceptions; the measure is based on the "residual" competence in Article 352 TFEU. NGOs have criticised the proposals for not covering meat from the offspring of cloned animals²⁶³.

Both proposed acts contain a clause according to which 5 years after the date of transposition of the directive MSs are to report on their experience with the directive and the EC is to present a report on this basis. No specific new labelling requirements are contained in the draft legislation. At the time of writing, neither of the two draft pieces of legislation has been adopted.

²⁵⁸ See U.S. Mission to the EU/USDA, Animal Cloning; available at: <http://www.usda-eu.org/topics/animal-cloning/>.

²⁵⁹ EP resolution of 3 September 2008 on the cloning of animals for food supply; available at: http://www.europarl.europa.eu/sides/getDoc.do?pubRef= //EP//TEXT+TA+P6_TA_2008_0400+0+DOC+XML+V0//EN.

²⁶⁰ Wiemer, Maria. EU Risk Governance of 'Cloned Food': Regulatory Uncertainty between Trade and Non-Trade. In *Balancing Between Trade and Risk: Integrating Legal and Social Science Perspectives*, edited by M. B. A. van Asselt, Esther Versluis, and Ellen Vos, 33–57, Routledge, 2013, p.52.

²⁶¹ See EFSA, Update on the state of play of Animal Health and Welfare and Environmental Impact of Animals derived from SCNT Cloning and their Offspring, and Food Safety of Products Obtained from those Animals, 5 July 2012; available at: <http://www.efsa.europa.eu/en/efsajournal/pub/2794.htm>.

²⁶² EC, Proposal for a Directive of the European Parliament and of the Council on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes, COM(2013) 892 final; available at: http://ec.europa.eu/food/food/biotechnology/novelfood/documents/proposal_2013-0433-cod_en.pdf.

²⁶³ BEUC, Food from cloned animals: consumers left in the dark, Press release, 18 December 2013; available at: http://www.beuc.org/publications/pr2013_028e_cloning_0.pdf.

7.2. Legislation in the US

In June 2001, the US Food and Drug Administration (FDA) first requested that animal clones and their progeny be kept out of the food supply until the agency had a chance to evaluate whether cloning posed any additional food consumption risks²⁶⁴. Food products in the US are governed by the provisions of the Federal Food, Drug and Cosmetic Act (FD&C Act)²⁶⁵ and regulations issued under its authority. Food products that are not “generally recognised as safe” (GRAS) are subject to pre-market review by FDA under the FD&C Act, as are new animal drugs.

In January 2008, following the completion of a multi-year risk assessment, the FDA determined that the sale of meat and milk products from cloning is safe²⁶⁶. The risk assessment concentrated on identifying the risks that cloning poses to animal health and welfare and to humans and animals consuming food derived from animal clones and their progeny²⁶⁷. FDA concluded that meat and milk from cow, pig, and goat clones and the offspring of any animal clones are as safe as food from conventionally-bred animals. FDA found insufficient information to reach conclusion on the safety of food from clones of other animal species, such as sheep. At the same time, the FDA also issued non-binding industry guidance and a risk management plan. FDA’s non-binding guidance for industry stated that meat or milk from cattle, swine, and goat clones do not require any additional controls compared with meat or milk from cattle, swine, or goats entering the food supply today²⁶⁸. The Risk Management Plan determined that should FDA identify any issues that would likely have an impact on food safety, it will take appropriate action, including consulting with the USDA, monitoring new data and technologies and consulting with clone producers²⁶⁹.

Following FDA’s approval of cloned animal products as safe, regulators at the USDA asked the livestock industry to continue the voluntary moratorium and to keep cloned animals themselves out of the food supply²⁷⁰. This voluntary moratorium remains in place today. USDA also announced that it would work to develop and implement a livestock cloning supply chain management programme and protocols for tracking cloned animals²⁷¹. However, these rules have not yet been proposed or implemented and it is unclear whether and to what extent the voluntary moratorium is being observed.

Prior to FDA’s approval of cloned animal products, officials reportedly encountered resistance from other US agencies regarding the consequences of cloned animals entering the US food supply and acceptance from trading partners, including the EU²⁷².

²⁶⁴ USDA, FDA's Final Risk Assessment, Management Plan and Industry Guidance on Animal Clones and their Progeny, Release No. 0011.08, January 2008.

²⁶⁵ FD&C Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301 (2006)).

²⁶⁶ FDA, FDA Issues Documents on the Safety of Food from Animal Clones, 15 January 2008; available at: <http://www.fda.gov/newsevents/newsroom/PressAnnouncements/2008/ucm116836.htm>.

²⁶⁷ FDA, Animal Cloning: A Risk Assessment, 8 January 2008.

²⁶⁸ FDA, Guidance for Industry Use of Animal Clones and Clone Progeny for Human Food and Animal Feed, No. 179, 15 January 2008.

²⁶⁹ FDA, Risk Management Plan for Clones and Their Progeny, 15 January 2008.

²⁷⁰ USDA, USDA Statement on FDA Risk Assessment on Animal Clones, Release No. 0012.08, 15 January 2008.

²⁷¹ USDA, Questions and Answers, FDA’s Final Risk Assessment, Management Plan and Industry Guidance on Animal Clones and their Progeny, January 2008; available at: <http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=2008/01/0011.xml>.

²⁷² Weiss, R., USDA Recommends That Food From Clones Stay Off the Market, Washington Post, 15 January 2008; available at: http://www.washingtonpost.com/wp_dyn/content/article/2008/01/15/AR2008011501555.html?hpid=topnews.

7.3. Main differences between EU and US legislation

In the US, no pre-market approval or labelling requirements exist. USDA has requested that producers continue to observe a voluntary moratorium and withhold from putting cloned animal products on the market, but there are in fact no binding rules or checks to ensure that this does not occur. Neither the FDA nor the USDA is tracking cloned animals to know if, when or where they are entering the food supply.

Under the EU's NFR, food products from cloned animals are subject to pre-market approval and to specific labelling requirements. No specific EU-wide requirements for animal cloning exist yet, but the proposed legislative acts – a Directive on the cloning of animals of bovine, porcine, ovine, caprine, and equine species kept and reproduced for farming purposes²⁶² and a Directive on the placing on the market of food from clones – would lead to a prohibition of animal cloning, as well as putting animal clones or products from such animals on the market. It would be illegal to import cloned animals or food products from cloned animals from countries where the technique is allowed and exists commercially, such as the US. There is no restriction in EU law on the marketing of products from the progeny of cloned animals and the EC draft of proposed legislation would not alter this state of affairs; however, the EP has regarded this as an essential issue requiring action.

The current lack of US restrictions and monitoring of cloned animal products could pose challenges to transparency and oversight of these products in case they would enter the EU market, particularly in the event of future EU legislation imposing restrictions on the offspring of cloned animals.

8. RAW MATERIALS AND ENERGY

KEY FINDINGS

- Neither the EU nor the US has adopted specific economy-wide binding rules on the environmental impacts of shale gas exploitation.
- EU and US regulations differ in terms of fuel carbon intensity standards and legislative approaches to imports to the EU of liquefied natural gas derived from US shale gas supplies. While increased imports are viewed by some as a potential contribution to improved EU energy security, concerns have also been expressed by US environmental NGOs²⁷³ that an increase in transatlantic trade in fuels could lead to increased production and resulting environmental impacts, including impacts to air and water quality and greenhouse gas emissions.
- Fuel quality legislation, and in particular the need for clear EU rules on calculating the GHG intensity of fossil fuels, has the potential to generate tensions in TTIP.

This section investigates requirements in selected EU and US regulations related to shale gas and automotive fuels, explains the differentiated treatment of fuels with regard to their carbon intensity, and compares the regulatory framework for shale gas exploitation on both sides of the Atlantic. Non-energy raw materials are not covered in this report, however issues related to securing undistorted access of critical raw materials have been analysed under the EC's Raw Material Initiative and Raw Materials Partnerships²⁷⁴. The focus on energy raw materials was selected as this is an area of interest to US investors (keen to engage in fuel trade with the EU) and the EU (given pressure to increase US imports of fuels as a substitute to fuels from Russia).

Automotive fuel quality regulations have already been subject to informal discussions under TTIP negotiations. US industry groups have tried to ensure this is considered as critically important within the negotiations²⁷⁵. US official statements so far do not directly refer to concrete EU legislation on the matter, but have expressed US partners' concerns about the lack of transparency and public consultation in the process²⁷⁶. The Commission's initial position paper on the TTIP negotiations in the area of raw materials and energy relates to trade in sustainable energy and the "right for each party to maintain or establish standards and regulations (...) while working, as far as possible, towards a convergence of domestic EU and US standards". Greater demand for trade, according to the EC, goes hand in hand with greater need for regulatory policies that promote sustainability²⁷⁷. Following the sixth round of TTIP negotiations, the two sides continued detailed exchanges of

²⁷³ See e.g. Sierra Club, No fracking way: now the EU-US trade deal risks expanding fracking, Issue Brief, March 2014; available at: [http://vault.sierraclub.org/trade/downloads/TTIP-ISDS-fracking-060314%20\(1\).pdf](http://vault.sierraclub.org/trade/downloads/TTIP-ISDS-fracking-060314%20(1).pdf).

²⁷⁴ See http://ec.europa.eu/enterprise/policies/raw-materials/index_en.htm and <https://ec.europa.eu/eip/raw-materials/en>.

²⁷⁵ American Fuel & Petrochemical Manufacturers, Comments on the Proposed Transatlantic Trade and Investment Partnership (TTIP) Negotiations with the European Union. [Federal Register Number 2013 07430 (April 1, 2013)], 10 May 2013; available at: <http://www.afpm.org/WorkArea/DownloadAsset.aspx?id=4031>.

²⁷⁶ US Trade Representative (USTR), Transcript: Chief Negotiators Dan Mullaney and Ignacio Garcia Bercero Hold a Press Conference Following the Fourth Round of Transatlantic Trade and Investment Partnership (TTIP) Negotiations, March 2014; available at: <http://www.ustr.gov/about-us/press-office/press-releases/2014/March/TTIP-Fourth-Round-Press-Conference-transcript>.

²⁷⁷ EC (2013), EU-US TTIP, Raw materials and energy, Initial EU position paper; available at: http://trade.ec.europa.eu/doclib/docs/2013/july/tradoc_151624.pdf.

information on their respective regulatory frameworks and focused on offshore risk management and safety²⁷⁸. This state of play may have evolved following the seventh round of negotiations which ended on 3 October 2014²⁷⁹.

8.1. Legislation in the EU

8.1.1. Shale gas extraction permits

There is no specific EU binding legislation on permits for or environmental regulation of shale gas extraction; however, a number of separate areas of EU legislation apply²⁸⁰. Some uncertainty had been present among national authorities and courts on the precise extent and requirements of the potentially relevant EU legislation; and differing approaches to permitting and regulation were being adopted at national level²⁸¹.

In response, and following both internal debate and lobbying from MSs, the EC decided not to propose a draft directive for consideration by Council and Parliament. Instead, it adopted Recommendation 2014/70/EU²⁸² in January 2014, laying down suggested minimum principles for exploration and production of unconventional hydrocarbons using hydraulic fracturing ("fracking"). The accompanying EC communication²⁸³ explains that this recommendation was aimed *inter alia* at providing clarity and predictability for market operators and citizens, and at ensuring that climate and environmental risks were fully considered.

The EC recommendation suggests that MSs should:

- ensure that a strategic environmental assessment is carried out before licenses are granted, and take the "necessary measures" to ensure that an environmental impact assessment is carried out for individual licenses, allowing for effective public participation in the process;
- set out clear rules for restrictions in, for example, flood risk and seismically active areas; and limitations in respect of depth distances from groundwater;
- require a detailed risk assessment before granting permits, which should be updated as necessary during operation; and require operators to maintain and apply risk management plans;
- only grant permits where the risk assessment shows that there will be no direct discharge of pollutants to groundwater, and no damage caused to other activities;

²⁷⁸ See EC, State of play of TTIP negotiations after the 6th round, 29 July 2014; available at: http://trade.ec.europa.eu/doclib/docs/2014/july/tradoc_152699.pdf.

²⁷⁹ No specific information was available at the time of writing this report; see <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1154> and <http://ec.europa.eu/trade/policy/in-focus/ttip/>.

²⁸⁰ Including: Environmental Impact Assessment (EIA) Directive (2011/92/EU); Mining Waste Directive (2006/21/EC); Water Framework Directive (2000/60/EC); REACH Regulation (1907/2006/EC); Biocides Regulation (528/2012/EU); Seveso II and III (under certain conditions) (96/82/EC and 2012/18/EU); potentially the Habitats (1992/43/EEC) and Birds (2009/147/EC) Directives; Environmental Liability Directive (2004/35/EC). In addition, the Hydrocarbons Licensing Directive (94/22/EC) applies, although its purpose is to ensure non-discrimination in the internal market, rather than environmental protection.

²⁸¹ Milieu (2013), Regulatory provisions governing key aspects of unconventional gas extraction in selected EU Member States, Final report prepared for the EC; available at: <http://ec.europa.eu/environment/integration/energy/pdf/Final%20Report%2024072013.pdf>.

²⁸² Commission Recommendation of 22 January 2014 on minimum principles for the exploration and production of hydrocarbons (such as shale gas) using high-volume hydraulic fracturing, OJ L 39, 8.2.2014, pp.72-78.

²⁸³ EC, Communication to the Council and the European Parliament on the exploration and production of hydrocarbons (such as shale gas) using high volume hydraulic fracturing in the EU, COM (2014) 23.

- assess environmental conditions before operations start, covering a broad range of factors (including water quality, air quality, soil conditions, seismicity, biodiversity, and the presence of methane in water) so that change can be monitored and liability determined in the event of an incident; and ensure adequate monitoring arrangements are in place;
- inform the public about the chemicals used for each well, and share the baseline data and monitoring results;
- require operators to use best available techniques to avoid or minimise environmental impacts, to minimise flaring and avoid venting of gases; and promote the responsible use of water resources; and
- apply the provisions of the Environmental Liability Directive to all activities at fracking installations.

The recommendation has no binding force; however, the EC has committed to review its effectiveness after 18 months, and decide whether to put forward proposals for legally binding provisions. The limited time since the recommendation's publication, and the limited nature of fracking operations in the EU, makes it difficult to assess the extent to which MSs are currently implementing all of its aspects.

In addition to the various pieces of EU binding legislation which apply to shale gas extraction,²⁸⁰ a number of MSs have adopted their own legislation or amended existing legislation in response to the development of fracking techniques. Some (e.g. France²⁸⁴, Bulgaria) have decided in principle not to allow shale gas exploitation using fracking; and others (UK, Poland²⁸⁵) have laid down specific requirements in relation to environmental impacts as part of a regime aimed at enabling shale gas exploitation. A report carried out for the EC and published in 2013²⁸¹ notes that while most MSs relied on general mining and environmental legislation, specific provisions or regulatory policies had been adopted in respect of Environmental Impact Assessments (Lithuania, Poland), air pollution from methane (UK, Denmark), or the treatment of wastewater.

Finally, while concerns have been raised about the implications of exploiting unconventional hydrocarbons for climate mitigation policies (both from the availability of new fossil fuels leading to the potential for greater cumulative carbon dioxide (CO₂) emissions; and from the impact of fugitive methane emissions), limited attention has been paid to the challenge of monitoring emissions from shale gas operations, and of ensuring that they are captured in the national greenhouse gas (GHG) emissions inventories required under the United Nations Framework Convention on Climate Change, although some inventory authorities have carried out some preliminary research²⁸⁶.

8.1.2. Fuel quality legislation

The core piece of EU law with regard to fuel quality is the Fuel Quality Directive (FQD, 2009/30/EC)²⁸⁷, which sets environmental requirements on GHG emissions, sulphur

²⁸⁴ Law No 2011-835 of 13 July 2011 (aiming at banning the exploration and exploitation of shale gas and repealing the exclusive research licences including projects using this technique).

²⁸⁵ Law of 11 July 2014, amending the Geological and Mining Law and certain other acts; See http://orka.sejm.gov.pl/proc7.nsf/ustawy/2352_u.htm.

²⁸⁶ See for example UK Informative Inventory Report (1980 to 2012): Annual Report for submission under the UNECE-Convention on Long-Range Transboundary Air Pollution, p.59.

²⁸⁷ Directive 2009/30/EC of the European Parliament and of the Council of 23 April 2009 amending Directive 98/70/EC as regards the specification of petrol, diesel and gas-oil and introducing a mechanism to monitor and reduce greenhouse gas emissions and amending Council Directive 1999/32/EC as regards the specification of fuel used by inland waterway vessels and repealing Directive 93/12/EEC, OJ L 140, 5.6.2009.

content, and additives as well as sustainability criteria for biomass. Similar criteria are also included in the Renewable Energy Directive (2009/28/EC).

Article 7a of the FQD places an obligation on fuel suppliers to reduce the GHG intensity of energy supplied for road transport. FQD implementing measures include guidance on calculating the GHG intensity of fossil fuels. The guidance should have been provided by the EC, but its first proposal (2011) was not approved by the required number of MSs. The lack of approval has been linked to an intensive lobbying campaign by Canada and the oil industry^{288,289}.

EU fuel quality legislation is supported by standards developed by the European Standardisation Organisation. The first set of European Standards (EN) for automotive fuels was adopted by all MSs in 1993. Three standards cover automotive fuel quality: EN 590 for diesel fuel, EN 228 for gasoline, and EN 589 for automotive liquefied petroleum gas (LPG). When requirements change the standards are updated. Since 2012 a new fuel standard is available (prEN 16214) establishing norms on sustainably produced biomass for energy applications.

EU fuel quality legislation aims at reducing GHG emissions and other air pollutants from transport, ensuring the correct functioning of a single fuel market, and ensuring that biofuels meet certain criteria for sustainable use. In addition, energy security concerns have driven the desire to diversify supply sources and improve efficiency of fuels²⁹⁰.

Under the FQD MSs are committed to reduce GHG intensity of transport fuels by 6 % by 2020 relative to 2010. The FQD has been criticised by environmental NGOs for lacking ambition and being supported by insufficient Implementing Measures expected from the EC.

In the context of TTIP, the future of FQD is of strategic importance. Depending on the level of ambition to achieve climate protection and other environmental standards, transatlantic trade in automotive fuels will be enhanced or restricted. This is linked to the (2011) FQD proposal on differentiation of the GHG intensity of different types of fuels. GHG intensity values help to assess if reduction targets set in the FQD are being met. According to the proposal, different fuels and feedstocks were accorded different "default values" for their carbon intensity. The proposed default values would mean that unconventional sources (such as coal-to-liquid, tar sands or oil shale) receive higher average GHG intensity values than conventional sources²⁹¹. The default values reflect partly emissions from extraction and processing of unconventional fuels²⁹². This approach however does not allow accounting for differences between the same type of fuel but with different extraction methods or product characteristics. Adoption of such stricter norms would therefore reduce the economic rationale for importing refined tar sands fuels from North America²⁸⁹.

²⁸⁸ C. Oliver, E. Crooks, Canada poised to dilute EU rules over tar sands oil, *Financial Times*, June 2014.

²⁸⁹ Brandt R., Upstream greenhouse gas (GHG) emissions from Canadian oil sands as a feedstock for European refineries, June 2011; Friends of the Earth Europe, *Dirty deals: How trade talks threaten to undermine EU climate policies and bring tar sands to Europe*, July 2014.

²⁹⁰ EC, A policy framework for climate and energy in the period from 2020 to 2030, COM (2014)15.

²⁹¹ The proposed default value for petrol made from conventional crude oil is 87.5 g CO₂/MJ. Petrol made from tar sands would equal 107 g CO₂/MJ; oil shale = 131.3 g CO₂/MJ; coal-to-liquid = 172 g CO₂/MJ; gas-to-liquid = 97 g CO₂/MJ, Consultation paper on the measures necessary for the implementation of Article 7a (5); See <http://ec.europa.eu/environment/air/transport/pdf/art7a.pdf>. Mainly based on EC JRC (2011), *Well-to-Wheels Analysis of Future Automotive Fuels and Powertrains in the European Context*, Version 3c, Report EUR 24952 EN.

²⁹² A study ordered by the EC demonstrated that GHG emissions from tar sands extraction and processing are about 23 % higher than the average for fuels used traditionally in the Europe.

The EU applies mandatory sustainability criteria to all biofuels used to deliver targets under the FQD and the Renewable Energy Directive. Compliance with these criteria is verified based on the EC accredited schemes. The criteria include requirement of GHG emissions from biofuels to be at least 35 % lower than from the fossil fuel they replace. From 2017 this increases to 50 % and 60 % from 2018 for new installations. The raw materials for biofuels cannot be sourced from land with high biodiversity or high carbon stock. The EP will also co-decide on the proposal for a directive amending the FQD by introducing indirect land use change (ILUC) consideration and promoting advanced, non-food biofuels²⁹³.

8.2. Legislation in the US

8.2.1. Shale gas extraction permits

The US is in the middle of an unprecedented “fracking” boom and projections show that by 2018 it will be a net exporter of natural gas²⁹⁴. Despite the surge in activity, regulation and permitting procedures for fracking lack federal guidance and get complex due to a growing patchwork of state- and local-level rules. The EPA has limited power to regulate fracking, based on applicable provisions in fundamental US environmental laws, although many of these laws have major exemptions for oil and gas production. Historically, EPA has not regulated the underground injection of fluids and, in 2004, the agency determined that unless diesel was used as an additive, fracking posed only a minimal threat to drinking water and thus regulation was unnecessary²⁹⁵. Subsequently, Congress enacted the Energy Policy Act of 2005, clarifying that underground injection control requirements in the Safe Drinking Water Act do not apply to fracking unless diesel fuel is used, in which case a permit is required²⁹⁶. In 2014, EPA issued guidance on diesel fuel injection during fracking, identifying chemical variations of diesel and outlining technical recommendations²⁹⁷.

Air emissions associated with fracking are regulated by EPA under the Clean Air Act (CAA), with categorical regulations for controlling volatile organic compounds (VOCs) and sulphur dioxide emissions from natural gas processing plants and air toxics standards for natural gas production, transmission, and storage facilities. In 2012, EPA adopted the first federal air standards for fracked natural gas wells²⁹⁸. The final standards will become applicable in 2015 and require the use of Reduced Emissions Completions or “green completions” on new wells, which is expected to attain a 95 % reduction in VOCs²⁹⁹. Gas wells are generally exempted from other CAA requirements³⁰⁰. The federal Clean Water Act, Resource Conservation and Recovery Act, National Environmental Policy Act (NEPA), and Comprehensive Environmental Response, Compensation, and Liability Act all have additional exemptions for fracking.

²⁹³ Proposal for a Directive of the European Parliament and of the Council amending Directive 98/70/EC relating to the quality of petrol and diesel fuels and amending Directive 2009/28/EC on the promotion of the use of energy from renewable sources, EP preparing for second reading.

²⁹⁴ EIA (2014), AEO2014 Early Release Overview; available at: http://www.eia.gov/forecasts/aeo/er/early_production.cfm.

²⁹⁵ EPA (2004), Evaluation of Impacts to Underground Sources of Drinking Water by Hydraulic Fracturing of Coalbed Methane Reservoirs Study.

²⁹⁶ Safe Drinking Water Act, 42 U.S.C. 1421(d).

²⁹⁷ See <http://water.epa.gov/type/groundwater/uic/class2/hydraulicfracturing/upload/epa816r14001.pdf>.

²⁹⁸ See <http://www.gpo.gov/fdsys/pkg/FR-2012-08-16/pdf/2012-16806.pdf>.

²⁹⁹ Oil and Natural Gas Sector: New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants Reviews, 77 CFR 49490, 16 August 2012.

³⁰⁰ Individual oil and gas wells and facilities are exempted from requirements that aggregate multiple small sources of air pollution located in close proximity as a “major source” subject to CAA regulations.

New federal regulations are under development. EPA is currently undertaking a major study regarding the impacts of fracking on drinking water resources, originally due in 2014 but now delayed until 2016³⁰¹. In 2013, the Bureau of Land Management published a revised proposed rule for fracking on public lands that would require disclosure of the chemicals used in the process after drilling is completed; the final rule has not yet been released³⁰². However, the majority of fracking takes place on private land and falls primarily under state regulation. There has been a substantial increase in fracking related legislation at the state and local levels in the US. Some states (e.g. New York and Vermont), as well as several local authorities, have enacted fracking moratoriums. California in 2013 passed a fracking regulation requiring companies to obtain permits, disclose chemicals used, and conduct well testing. Pennsylvania has implemented state law requirements for impact fees, allowing doctors (but not patients) to access lists of chemicals used in certain situations, and barring local governments from legislating on fracking. Local level bans and restrictions on fracking or associated flaring are becoming common in a number of states including New York, Colorado, California, Ohio and North Dakota³⁰³.

The US Natural Gas Act, as amended in 1992, requires the US Department of Energy (DOE) to automatically approve all liquefied natural gas (LNG) shipments to or from countries with which the US has a free trade agreement that calls for so-called "national treatment for trade in gas"³⁰⁴. Countries that do not have a free trade agreement with the US are granted export authorisations unless DOE finds that the proposed exports "will not be consistent with the public interest." In June 2014, DOE proposed to reform the process it uses for determining whether exports are in the public interest, requiring projects to first complete federal environmental reviews³⁰⁵. Natural gas liquefaction facilities and export terminals are subject to additional federal environmental laws and permitting requirements such as the Endangered Species Act, the Coastal Zone Management Act, and the CAA, including permitting requirements for major sources of GHG emissions³⁰⁶.

8.2.2. Fuel quality legislation

One of the primary mechanisms for regulating fuel quality in the US is through the Control of Air Pollution From Motor Vehicles: Tier 3 Motor Vehicle Emission and Fuel Standards developed under the CAA³⁰⁷. The Tier 3 standards restrict the content of some air pollutants in fuels (e.g. sulphur), but do not regulate GHG emissions. The federal Renewable Fuel Standard 2 (RFS2)³⁰⁸ and California Low Carbon Fuel Standard (LCFS) both regulate the carbon intensity of transportation fuels and use similar approaches for

³⁰¹ EPA (2012), The Potential Impacts of Hydraulic Fracturing on Drinking Water Resources: Progress Report, December 2012; available at: <http://www2.epa.gov/hfstudy/potential-impacts-hydraulic-fracturing-drinking-water-resources-progress-report-december>; Fuel Fix (2013) Fed: fracking study won't be done until 2016, 19 June 2013; available at: <http://fuelfix.com/blog/2013/06/19/fed-fracking-study-wont-be-done-until-2016/>.

³⁰² BLM (2013), Oil and Gas: Hydraulic Fracturing on Federal and Indian Land, 78 Fed. Reg. 31636, 24 May 2013.

³⁰³ Barrett, C. (2014), 2014 Should Be Pivotal For Fracking Regulation, Law 360; available at: <http://www.law360.com/environmental/articles/508609/2014-should-be-pivotal-for-fracking-regulation> WSJ North Dakota's Latest Fracking Problem, June 2014.

³⁰⁴ Natural Gas Act, 15 U.S.C. 717b(c).

³⁰⁵ DOE (2014) Proposed Procedures for Liquefied Natural Gas Export Decisions. 79 Fed. Reg. 32261, 4 June 2014.

³⁰⁶ Prevention of Significant Deterioration and Title V Greenhouse Gas Tailoring Rule, 75 Fed. Reg. 31514, 3 June 2010; 40 C.F.R. §52.21.

³⁰⁷ Control of Air Pollution From Motor Vehicles: Tier 3 Motor Vehicle Emission and Fuel Standards, 79 Fed. Reg. 23413, 28 April 2014.

³⁰⁸ The Renewable Fuel Standard (RFS1) was first created in 2005 as part of the Energy Policy Act of 2005 and later amended and revised as part of the Energy Independence and Security Act of 2007 (RFS2).

measuring Life Cycle Assessment (LCA) of fuels, albeit with differing goals and results. The RFS2, which seeks to increase US energy independence, applies to importers, refiners, and blenders of gasoline and diesel fuel in the US. It sets targets of minimum renewable fuel share each year in the transport sector, reaching 36 billion gallons by 2022, of which 21 billion must be advanced biofuels. The RFS2 takes into account emissions from ILUC, transportation, cultivation and production via various modelling approaches. The State of California is considering how sustainability criteria might be represented in its legislation, and RFS2 applies some similar requirements as the EU regulations on biofuels sustainability³⁰⁹.

The RFS2 also defines the federal fuel baseline lifecycle GHG emissions as the 2005 average of gasoline or diesel sold or distributed in the US. The 2005 baseline takes into account emissions from extraction³¹⁰. Both the RFS2 and LCFS account for emissions from ILUC. The most recent estimates on the GHG gas intensity for tar sands oil provided by the Congressional Research Service assume a 17 % greater well-to-wheels emissions factor compared to the 2005 EPA US average. If the share of tar sand oil in the US average increases – possibly linked to the construction of the Keystone XL pipeline – then the EPA could at some point also update the reference GHG lifecycle intensity of gasoline. However, there is no update scheduled so far. Due to the significant time lag and the indirect nature of this relationship, there is little resulting regulation on tar sand oil and imports, and carbon intensity of imports into the US in general. California's LCFS is fuel and technology neutral. It requires a reduction of carbon intensity of the fuel mix used in the transport sector by 10 % by 2020, relative to 2010 emission levels³¹¹. This reduction can be achieved through the use of alternative fuels, including biofuels, hydrogen, and electricity. Several other US states are also developing low carbon fuel standards³¹².

While there are various assessments of the GHG intensity of fuels (including those derived from tar sand oil), US fuel legislation does not directly address the issue of GHG emissions from tar sand oils. New light duty vehicles and heavy duty vehicles are subjected to fuel efficiency regulations³¹³. Regulations convert actual fuel consumption into GHG emissions using EPA emission factors. These factors are updated in intervals and take into account the direct GHG emissions of fuels only, not upstream emissions from transport, ILUC or extraction.

8.3. Main differences between EU and US legislation

While there are significant differences between the EU and US in regulatory standards for shale gas exploration and exploitation, the key similarity is the absence of a single economy-wide regulatory framework for unconventional gas. The regulatory differences that do exist on environmental issues appear to present limited implications for investment in the exploitation of EU shale deposits; any investors would need to comply with relevant EU and national legislation. Harmonisation of regulatory standards in response to TTIP appears unlikely in the absence of specific standards at EU or US level; however, the existence of the EC recommendation and the framework it establishes would appear to make it the logical starting point.

³⁰⁹ ICCT, Upstream emissions of fossil fuels feedstocks for transport fuels in the European Union, 2014.

³¹⁰ Department of Energy: National Energy Technology Laboratory (2009), NETL: Petroleum- Based Fuels Life Cycle Greenhouse Gas Analysis— 2005 Baseline Model.

³¹¹ California Code of Regulations, Title 17, §§ 95482–95485.

³¹² See C2ES (2014), Low Carbon Fuel Standards, Center for Climate and Energy Solutions; available at <http://www.c2es.org/us-states-regions/policy-maps/low-carbon-fuel-standard>.

³¹³ The 2017 and Later Model Year Light-Duty Vehicle Greenhouse Gas Emissions and Corporate Average Fuel Economy Standards (CAFE 2012), Regulation for Heavy-Duty Engine and Vehicle, and Non-road Technical Amendments (HD 2013).

In terms of fuel quality regulations the main differences between the EU and US regulations relate to GHG intensity standards and their tracking methods. The EC is required to develop an FQD Implementing Measure laying out a complementary methodology for the calculation of GHG emissions from fossil fuels. There are several US produced fuels whose import could be restricted or reduced depending on FQD implementation. An additional difference related to ILUC that is still not accounted for in the EU (legislation pending), whereas in the US it constitutes a part of fuel quality requirements.

The main trade implications of differing legislative approaches on shale gas arise in relation to imports to the EU of LNG derived from shale gas supplies in the US. The 2014 EU-US summit conclusions refer to this as a potential contribution to improved EU energy security (implicitly, by diversifying the EU's gas supply sources)³¹⁴, and the EC's communication on energy security³¹⁵ refers to benefits from investment in new LNG terminals as a contribution to diversification of supplies. A concern raised by US environmental groups²⁷³ is that increased trade of natural gas will spur increased production and resulting environmental impacts, including local impacts to air and water quality and GHG emissions from both shale gas extraction and from the energy intensive liquefaction process and transport.

FQD requirements are likely to remain a controversial topic on the TTIP agenda. Potential conflicts may arise around GHG labelling and tracking. Oil industry groups may lobby to safeguard access to the EU market for unconventional oils. Against this background TTIP potentially creates risks of delayed or weakened future ambition of EU environmental regulation (e.g. a failure to introduce a separate GHG intensity value for tar sands oil; or the absence of FQD requirements in the Climate and Energy Framework beyond 2020), since such measures could be seen as introducing new barriers to trade, or deepening existing barriers.

³¹⁴ The White House, EU US Summit: Joint Statement, 26 March 2014; available at: <http://www.whitehouse.gov/the-press-office/2014/03/26/eu-us-summit-joint-statement>.

³¹⁵ EC, European Energy Security Strategy, COM (2014) 330 final, 28 May 2014.

9. MOTOR VEHICLES

KEY FINDINGS

- While there are already broad similarities between EU and US emission standards, the overall impact of regulatory differences was estimated in 2009 to have an impact equivalent to an ad valorem tariff of 26.8 %³¹⁶.
- Standards in both the US and EU are dynamic, with scope for regular improvement based on technological developments. Mechanisms for ensuring that future improvements in standards can be implemented will be an important consideration.
- TTIP negotiations on motor vehicles are already well advanced; both sides consider that mutual recognition of emission standards and other environmental regulations for the automotive industry could provide significant benefits.

In the context of TTIP, a lack of convergence of environmental regulations between the EU and US can have equivalent effects on tariffs. The stakes are high for harmonising relevant standards. EU – US trade in automotive goods accounts for about 10 % of total sales between the two regions, and an ambitious joint approach could influence standards in other markets. Enabling component manufacturers in particular to develop products which will be relevant to meeting emission standards in both the EU and US could encourage innovation. While an approximation of existing standards without weakening ambition has clear benefits, future legislation to tighten standards (for example to meet progressive CO2 emission reductions targets for 2030 and beyond) may create new potential for divergence.

This summary covers standards on vehicle emissions to air. Usually standards differ according to vehicle manufacturer's annual production period, known as a model year (MY). It does not cover safety elements of the type approval process for certifying vehicle models, or the EU's End-of-Life Vehicles Directive requirements on the use of specific hazardous substances in new vehicles.

Efforts to harmonise the US and EU automotive regulations have been underway for decades, however no significant progress has been made in the past 20 years. The EU and US cooperate on this issue within the United Nations Economic Commission for Europe (UNECE) aiming at enhanced convergence of standards through Global Technical Regulations. The US however did not sign the United Nations agreement of 1958 by which the parties commit to mutual recognition of approvals for vehicle components.

Cooperation on trade issues in the automotive industry between the EU and the US is already relatively advanced³¹⁷. In a joint declaration President Obama and President Barroso announced that TTIP should aim at aligning US and European automotive safety and environmental standards³¹⁸. The two sides are engaged in exchanges on their

³¹⁶ ECORYS (2009), Nontariff measures in EU-US trade and investment – an economic analysis, Final Report commissioned by the EC, OJ 2007/S 180-219493; available at: http://trade.ec.europa.eu/doclib/docs/2009/december/tradoc_145613.pdf.

³¹⁷ EC (2014), EU-US TTIP, EU position on motor vehicles; available at: http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152467.pdf.

³¹⁸ EC, Statement from United States President Barack Obama, European Council President Herman Van Rompuy and European Commission President José Manuel Barroso Brussels/ Washington, 13 February 2013, MEMO/13/94.

regulatory systems, the scope and approach for equivalence of existing regulations, with respect to cooperation under the UNECE. Both regions are committed to address regulatory divergences without lowering environmental protection levels³¹⁹. This may have evolved further following the seventh round of negotiations which ended on 3 October 2014³²⁰.

9.1. Legislation in the EU

The technical requirements related to the type approval system for motor vehicles were established as early as 1970; they initially had the aim of removing barriers to the internal market, but have increasingly aimed at ensuring high levels of environmental and consumer protection. The EU applies mandatory emission reduction targets and emission standards for new cars and light commercial vehicles (LCV). The law for both types of vehicles is similar.

9.1.1. Emission performance standards

The main legal act on vehicle emissions is Regulation 715/2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information³²¹. All the technical specifications are laid down by implementing measures adopted in comitology procedures. These consist of dozens of acts adopted in form of EC Regulations or Directives (for example, the EC has adopted regulations amending a number of legislative acts with regard to: emissions from light passenger and commercial vehicles (Euro 6), monitoring of particulate emissions, and innovative technologies for reducing CO₂ emissions)³²².

The Euro 5 and 6 standards have been introduced for cars and LCV with respect to a number of pollutants including: carbon monoxide (CO), hydrocarbons, nitrogen oxides (NO_x), and particulate pollutants. Since 2011 all new cars and LCV have to comply with Euro 5 standards. EU regulations introduce different emission limits for compression ignition (diesel) and positive ignition (e.g. gasoline, NG, LPG, and ethanol) vehicles. Diesels have more stringent carbon oxides (CO_x) standards but are allowed higher NO_x than positive ignition engines. Sulphur-free diesel and gasoline fuels (≤ 10 ppm S) became mandatory from 2009. The Euro 6 standard will set even lower emission limits. It will be binding for the registration and sale of new types of cars and LCV as of September 2015. Emissions are tested over the New European Drive Cycle (chassis dynamometer) procedure.

9.1.2. CO₂ emission performance requirements

EU policy on achieving CO₂ reductions from passenger cars has evolved gradually since 2000. Initially, legislation focussed on monitoring emissions, with action to reduce them based on a set of voluntary agreements. However, while carbon efficiency of vehicles improved, it did not keep pace with targets, and mandatory requirements were introduced.

³¹⁹ EC, The Transatlantic Trade and Investment Partnership - Regulatory Issues : EU position on motor vehicles, May 2014; available at: http://trade.ec.europa.eu/doclib/docs/2014/may/tradoc_152467.pdf.

³²⁰ No specific information was available at the time of writing this report; see <http://trade.ec.europa.eu/doclib/press/index.cfm?id=1154> and <http://ec.europa.eu/trade/policy/in-focus/ttip/>.

³²¹ Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information, OJ L 171, 29.6.2007, pp.1-16.

³²² Commission Regulations (EU): No 627/2014, No 195/2013, No 459/2012.

The EU legislators adopted two regulations providing for comprehensive CO₂ reduction targets for passenger cars and LCV: Regulation 443/2009 setting emission performance standards for new passenger cars³²³, and Regulation No 510/2011 setting emission performance standards for new light commercial vehicles³²⁴. In July 2012, the EC put forward two regulatory proposals to set mandatory CO₂ standards for new cars and LCV in 2020. After the approval of the proposals by the EU legislator bodies, amendments to relevant regulations were passed in 2014.

Legislation establishes CO₂ reduction targets for the average emissions from 2012 car MY. For MY 2012-2019 the target is 130 g/km with all fleet to reach it by 2015³²⁵. For MY 2020 and later the target is 95 g/km with all fleet to reach it by 2021. These targets are divided into sub-targets binding each year.

In terms of fuel economy, the 2015 target is approximately equivalent to 5.6 L/100 km of petrol or 4.9 L/100 km of diesel. The 2021 target equates to approximately 4.1 L/100 km of petrol or 3.6 L/100 km of diesel.

For LCV the EU set CO₂ emission targets in 2011. European regulator limits CO₂ emissions from new LCV to a fleet average of 175 g/km by 2017 for cars MY 2014 and older. The target by 2020 is 147 g/km. In terms of fuel economy, the 2017 target is approximately equivalent to 6.6 L/100 km of diesel. The 2020 target equates approximately to 5.5 L/100 km of diesel³²⁶.

9.2. Legislation in the US

9.2.1. Federal emission standards

At the federal level emissions from motor vehicles are regulated under two major programmes, coordinated between each other. One of the programmes deals with CO₂ emissions and boosting fuel economy, while the other aims at curbing other tailpipe and evaporative emissions.

Emission standards for passenger cars and LCV, including emission standards for GHG emissions, are established by the EPA. The EPA regulates automotive emissions according to the provisions of the CAA.

To reduce the environmental impact of the automotive sector the US aims to increase transport energy efficiency. This is procured by means of fuel economy standards developed by the National Highway Traffic Safety Administration. Fuel economy standards are set in Corporate Average Fuel Economy (CAFE) legislation.

³²³ Regulation (EC) No 443/2009 of the European Parliament and of the Council setting emission performance standards for new passenger cars as part of the Community's integrated approach to reduce CO₂ emissions from light-duty vehicles, OJ L 140, 5.6.2009, pp.1-15.

³²⁴ Regulation (EU) 510/2011 of the European Parliament and of the Council of 11 May 2011 setting emission performance standards for new light commercial vehicles as part of the Union's integrated approach to reduce CO₂ emissions from light-duty vehicles, OJ L 145, 31.5.2011, pp.1-18.

³²⁵ According to the European Environmental Agency, CO₂ emissions from new cars sold in 2013 fell 4 % to an average of 127 grams per kilometre (g/km), therefore the binding target of 130g/km set for 2015 has been met 2 years early.

³²⁶ International Council on Clean transportation, EU CO₂ emission standards for passenger cars and light-commercial vehicles, January 2014.

The core regulatory acts on CO₂ emission standards and CAFE for passenger cars and LCV are: the Regulation of 2010 setting standards for MY 2012-2016 and the Regulation of 2012 for MY over 2017-2025³²⁷.

Federal CO₂ emission standards

The CO₂ emission standards are set for each MY car over 2012-2016 and 2017-2025. Each vehicle has a different CO₂ emissions compliance target depending on its CO₂ emission footprint value, related to the size of the vehicle. Current regulations establish the following CO₂ emissions standards per MY, progressing from 263 g/mile (163.4 g/km) in 2012 to 143g/mile (88.9 g/km) in 2025 for passenger cars, and from 346 g/mile (215.0 g/km) in 2012 to 203 g/mile (126.1 g/km) in 2025 for LCV.

Other Federal emission standards

Emissions other than CO₂ are subject to two regulations adopted in 2014: on Motor Vehicle Emission and Fuel Standards and Tailpipe and Evaporative Emission and Vehicle Fuel Standards³²⁸. Tier 3 is planned for phasing-in over 2017-2025 MY³²⁹. Standards apply to sulphur content of gasoline as well as emissions of non-methane organic gases, NO_x, PM, CO, and air toxics. The same emission limits apply to all vehicles regardless of the fuel they use. Caps for tailpipe nitrous oxide and methane emissions have been set above the current emission levels from passenger cars or LCV and they play a preventive role. Sulphur standard levels in gasoline are similar to levels already being achieved in the EU. Sulphur standard levels for diesel of 10 ppm will take effect in 2017. Vehicles are tested over the FTP-75 (Federal Test Procedure).

Corporate Average Fuel Economy

Current regulations also establish fuel economy reduction targets per MY progressing from 29.7 miles per gallon (mpg) in 2012 (approx. 7.92 l/100km) to 54.5 mpg (approx. 4.32 l/100km) in 2025 for combined passenger cars and LCV.

9.2.2. California emission standards

California is the only US state vested by EPA with authority to adopt its own emission regulations, because its regulatory activity predates federal action³³⁰. California regulations related to emissions are developed and adopted by the California Air Resources Board within the Californian EPA. Other states can choose between the federal emission standards or California requirements. Apart from air quality and energy efficiency considerations, the US regulator explicitly aims at lowering fuel costs for car users. Cost efficiency justified action on GHG before the EPA's decision to treat them as a harmful pollutant.

California emission standards are more stringent than federal requirements, but the structure of both is similar. Apart from usual objectives, the environmental regulations aim at boosting fuel cells (both electric and plug-in hybrid) commercialisation and help meet

³²⁷ EPA/NHTSA Final Rulemaking: Model Year 2012-2016 Light-Duty Vehicle Greenhouse Gas Emissions Standards and Corporate Average Fuel Economy Standards, 25324 Federal Register / Vol. 75, No. 88 / Friday, May 7, 2010 / Rules and Regulations and EPA/NHTSA Final Rulemaking to Establish 2017 and Later Model Years Light-Duty Vehicle Greenhouse Gas Emissions and Corporate Average Fuel Economy Standards, 62624 Federal Register / Vol. 77, No. 199 / Monday, October 15, 2012 / Rules and Regulations.

³²⁸ EPA, EPA Sets Tier 3 Motor Vehicle Emission and Fuel Standards, Office of Transportation and Air Quality, EPA-420-F-14-009, March 2014.

³²⁹ EPA, Control of Air Pollution From New Motor Vehicles: Tier 3 Motor Vehicle Emission and Fuel Standards, EPA-HQ-OAR-2011-0135.

³³⁰ California State Motor Vehicle Pollution Control Standards; Notice of Decision Granting a Waiver of Clean Air Act Pre-emption for California's 2009 and Subsequent Model Year.

the state's goal of 15 % of new vehicle sales being composed of these technologies by 2025³³¹. The major regulatory measures for California emission standards include Low Emission Vehicle (LEV) II regulations phased-in through MY 2004-2010 and adopted by number of other US states and LEV III regulations to be phased-in through MY 2015-2025. Beginning with model year 2020, all vehicles must be certified to LEV III. The same standards for gaseous pollutants apply to diesel- and gasoline-fuelled vehicles. PM standards apply to diesel vehicles only. Under LEV III all passenger cars and LCV will have to meet a "zero" evaporative standard, while using challenging test fuels.

9.3. Main differences between the EU and US legislation

Vehicles in the US must meet federal emissions and fuel economy rules plus California's stricter standards. European-market cars must be Euro 5/6 compliant. Regulations in both regions strive for environmental protection and fuel-efficiency, however contain a number of differences as set out in the table below.

Table 1 - Main differences between EU and US environmental standards for motor vehicles

Area	EU	US
CO ₂ reduction targets	More stringent ³³²	Less stringent
Emission standards (g/km):		
• Nitrogen oxides (NOx)	0.06(gasoline);0.18(diesel)	0.04
• Non-methane organic gases (NMOG)	0.07(gasoline);0.09(diesel)	0.06
• Carbon monoxide (CO)	0.5	2.6
• Greenhouse gases (GHG, in 2016)	129.3	155.4
• Greenhouse gases (GHG, in 2020)	94.5	132.4
Fuel economy standard	No	Yes
Mutual recognition through UNECE	Yes	No
Fuel/ignition type differentiation	Yes	No
Limits on NOx emissions from diesel engines	Less stringent	More
Testing methods	New European Drive Cycle procedure	Federal Test Procedure

Source: Canis B., Lattanzio R. K., U.S. and EU Motor Vehicle Standards: Issues for Transatlantic Trade Negotiations, Report prepared for members and committees of Congress, February 2014.

³³¹ California Health and Safety Code.

³³² The differences remain within the range of 20 g/km (for example 95g/km by 2015 for passenger cars in EU compared with 106, 9 g/km for the same car category by 2015 in US).

Neither the EU nor the US intend to lower environmental standards for the automotive industry and both plan to introduce more stringent regulations in this area³³³. The TTIP negotiations thus provide a good opportunity for enhanced cooperation on alignment and/or mutual recognition of environmental standards. Both parties have already agreed on desirable future developments and intend to further use the UNECE platform to strengthen international rules. EU and US regulators will perform an assessment of equivalence of regulations based on data provided by industry and others. Regulators are to take a pragmatic approach based on the outcomes of regulations, rather than on absolute values of technical specifications. A list of converging regulations will be established. Certification schemes and other conformity assessments will be facilitated but not harmonised. However potential areas of conflict may arise when discussing common ground in certain areas, particularly on emission standards for diesel engines and CO₂ reduction targets.

³³³ EC, State of play of TTIP negotiations after the 6th round, 29 July 2014; available at: http://trade.ec.europa.eu/doclib/docs/2014/july/tradoc_152699.pdf.

10. CONCLUSIONS

In general, TTIP negotiators will have to consider the numerous differences that exist between EU and US legislation in order to reach consistent convergence and/or harmonisation of standards while ensuring the protection of the environment and human health and safety. However, the degree of divergence between the regulatory systems on both sides of the Atlantic, and thus the development of future requirements and the potential for collaboration varies across different areas.

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

In other areas, the **main differences are a result of diverging approaches** to risk analysis which may also be difficult to bridge. This is notably the case in the food and nutrition sector with regard to the approach taken to risk regulation of food safety. The EU applies the precautionary principle, which allows for regulatory action to be taken in the case of scientific uncertainty, whereas the US requires sound scientific evidence of harmful effects. The same applies in the case of marketing approval of plant protection products (PPPs). When considering convergence of regulations it may also be important to compare the scientific requirements imposed. Such scientific comparison did not fall within the scope of this study; however, for instance, in the case of medicinal products for human use, it could be interesting to compare scientific aspects and requirements of the environmental (risk) assessment which must accompany a marketing authorisation application.

In areas where **differences are mainly of a technical nature** (e.g. technical environmental standards for motor vehicles); greater convergence could potentially be achieved through increased technical cooperation or through mutual recognition of environmental regulations in place (provided there is no lowering of the level of environmental protection).

Finally, in areas where **there are currently no binding regulations on either side of the Atlantic**, convergence may be easier to achieve through scientific and technical cooperation and better coordination of EU and US regulators. This is notably the case for nanomaterials (NMs) for which there are currently no specific legislation in place in either the US or the EU, although the EU imposes some labelling requirements.

More specifically and with regard to the areas addressed in the previous chapters, the study has led to the following findings:

- **Medicines for human use and medical devices:**
 - The marketing authorisation (MA) process for pharmaceuticals dedicated to human use is often decentralised in the EU, contrary to the US where the process is highly centralised. In addition, although an environmental assessment is required in the application dossier for medicines on both sides, in the EU the environmental risk assessment (ERA) has no impact on the risk-benefit analysis whereas comments received following publication of an environmental impact statement (EIS) may lead the US Food and

Drug Administration (FDA) to consider beginning an action to withdraw the approval. Furthermore, the difference between confidential and non-confidential information is more precise in the US legislation than in the EU.

- The marketing process for medical devices is also centralised in the US (through the FDA), whereas it is decentralised in the EU, with stricter requirements in the US than in the EU. However, the EP proposed, in its amendments to the EC's Proposal for a Regulation on medical devices, the creation of a more centralised marketing approval system for high risk medical devices. An environmental assessment (and an EIS as the case may be) is required in the US (similar to what is required for pharmaceuticals) but there is no such specific requirement in the EU. Finally, information on medical devices may not be freely and publicly accessible. For instance, in the EU a centralised European databank for medical devices (Eudamed) has been developed which is only accessible to MS' competent authorities, not to the public. In its report on the Proposal for a Regulation on medical devices, the EP intends to increase the availability of information to the public, provided it does not constitute commercially sensitive information. By contrast, in the US the FDA is required to make publicly available some information, after deletion of information that constitutes a trade secret or confidential commercial or financial information.
- **Cosmetics:** The legal systems regulating the authorisation for marketing cosmetics are different in the EU and the US. In particular, all substances used in cosmetic products are subject to a stringent safety assessment before being placed on the EU market, such an assessment is not mandatory in the US. The EU procedure for proving the limited risk to human health involves complying with strict obligations such as the ban of animal testing which is, by contrast, allowed by US legislation under specific circumstances. In addition, EU manufacturers must register and label all cosmetic substances and finished cosmetic products placed on the market; this is voluntary in the US.
- **Food and nutrition:** The EU and US systems for food product traceability diverge in scope, with the EU taking a more comprehensive, preventive approach (known as the "farm to fork" approach") than the current US system which focuses on registered facilities. However, the US Food Safety Modernization Act mandates a stricter, risk-based approach and rigid recordkeeping rules so the new product tracing system which the FDA is currently developing will likely increase in scope and stringency. Risk analysis for food safety continues to differ between the US and EU due to the US using a strictly science-based approach and the EU using the precautionary principle, which allows regulatory action even in the absence of scientific certainty on risks. Nutrition and health claim labelling on food products differs between the US and EU in terms of the scientific regulatory approval process. The scientific evidence submitted by the petitioning firm or through the FDA's literature search must demonstrate significant scientific agreement in the US for the health claim to receive approval, while the EU allows for additional consideration of stakeholder and consumer opinion. In addition, US products with structure/function claims are allowed on the market prior to FDA approval, and labels may contain qualified health claims provided some "credible" science can support the claim and an accompanying qualifying statement is included.

- **Sanitary and phyto-sanitary (SPS) measures:** The evaluation of potential adverse effects on animal and human health and the environment due to the use of plant protection products (PPPs) is the main element of the MA of PPPs on either side of the Atlantic. However, contrary to the EU, the US also considers the cost-effectiveness of PPPs in addition to the scientific risk assessment, which may weigh in favour of approval of the PPPs. The nature of supporting studies and the renewal period for marketing authorisation also diverge between both sides. Regarding risk mitigation measures, the EU takes account of factors such as scientific uncertainty when making decisions, in line with the precautionary principle, while the US approach is based on robust scientific assessment prior to implementing actions to address risks.
- **Nanomaterials:** Currently, the legal framework for the use of NMs and products containing NMs is implicitly taken into account in general legislation on chemicals, namely Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) in the EU and the Toxic Substances Control Act (TSCA) in the US. These regulations differ on several points, in particular regarding the submission of safety data which is mandatory in the EU and, by contrast, requested under specific conditions in the US. In addition, strict requirements of registration and labelling apply in the EU for categories of products that are potentially manufactured from NMs, including food additives, cosmetics and biocides. Moreover, some NM registration rules have already been implemented in several EU MSs. However, the development of a definition of NMs approved at international level and discussions on specific legislation dedicated to NMs is ongoing on both sides of the Atlantic.
- **Cloning:** Differences in US and EU approaches to cloning, possibly reflect general differences in approaches to dealing with emerging and potentially risky new technologies. In the EU, there is currently no dedicated framework for cloning, for the marketing of products from cloned animals and the offspring of cloned animals. Marketing products from cloned animals would be subject to approval under the Novel Food Regulation; however no requests have been received to date. A new legislative framework, including a built-in review after five years, has recently been proposed which would outlaw animal cloning and the marketing of products from such animals, but not the marketing of the products from the offspring of cloned animals. The latter remains controversial in the EU. In the US, the FDA determined that cloned animal products are safe; nonetheless, regulators at the USDA have asked the livestock industry to continue the voluntary moratorium and to keep cloned animals out of the food supply. This voluntary moratorium remains in place today. However, the lack of US monitoring and labelling of cloned animal products obstructs oversight of imports of these products to the EU and other markets.
- **Raw materials and energy:** Neither the US nor the EU has adopted specific, economy-wide binding legislation on the exploitation of shale gas. An approximation of regulatory standards for shale gas extraction is therefore unlikely at this stage. However, the 2014 Commission recommendation could be a logical starting place for a discussion on approximation of legislation. Fuel quality legislation, and in particular the need for clear EU rules on calculating the GHG intensity of fossil fuels, has the potential to generate tensions in TTIP.

- **Motor vehicles:** Among the numerous diverging technical and environmental standards for motor vehicles, CO₂ reduction targets are more stringent in the EU than in the US. In addition EU standards on CO₂ emissions from motor vehicles are more restrictive than US standards; although for some air quality pollutants US standards are stricter (e.g. nitrogen oxides). Cooperation between the EU and the US on approximation of regulatory approaches, without reducing environmental ambition is well advanced and on-going through further use of the United Nations Economic Commission for Europe platform.

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ISBN 978-92-823-6137-5 (paper)
ISBN 978-92-823-6136-8 (pdf)

doi: 10.2861/73027 (paper)
doi: 10.2861/73002 (pdf)