



Recommendations to the Estonian Presidency of the Council of the European Union

July - December 2017





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Message to the Estonian Presidency of the Council of the European Union



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Estonia assumes the Presidency of the Council of the EU for the first time since joining in 2004 at a testing time for Europe and the world. In the face of global challenges such as growing anti-trade rhetoric, rising populism, migration and sluggish economic growth, political leadership will be critical to steer Europe through the second half of 2017. The EU is sailing through uncharted waters, redefining its relationship with the UK and facing rising levels of anti-EU sentiment in the Member States. We will need a strong and consensus-building Presidency to restore much-needed confidence in the EU's ability to deliver for its citizens and to play a key role on the world stage.

Last March European leaders gathered to celebrate the 60th anniversary of the Treaty of Rome, reminding us that European unity started as the dream of the few, but has become the hope of the many and that we cannot take the EU's achievements for granted. Just like the critics of Europe, we need to speak out to tell the story of Europe and what it has brought to its citizens.

With this in mind, we very much welcome the Estonian Presidency's focus on an open and innovative European economy. We believe that Europe has benefited from being an open economy and that trade is a catalyst for growth and job creation. The Estonian Presidency's emphasis on a Digital Europe and the free flow of data is critical to bringing more innovation, technologies and services to the European economy. As a digital leader in Europe, Estonia not only has a great story to tell but also a tremendous amount of experience in this area that will be essential to moving these priorities forward.

In the current uncertain international environment, the case for strong transatlantic cooperation remains as compelling as ever and as a supporter of a strong transatlantic partnership we are confident that the Estonian Presidency will make this a priority. The EU and the US are the drivers of global growth. Our economic partnership is vibrant: it represents the largest and wealthiest market in the world. Aggregate US investment in Europe totalled more than €2 trillion in 2016 and directly supports more than 4.5 million jobs in Europe.

We are looking forward to working closely with Estonia before, during and after the Presidency to ensure we reach our common objectives of a stronger and more competitive Europe to create jobs, meet consumers' needs and generate wealth for its citizens. This is why I am delighted to present these recommendations to the Estonian government on behalf of AmCham EU and our 155 member companies. We hope they will provide concrete input and direction to the Presidency's work programme. We believe that many of the issues raised by AmCham EU in this report are vital to creating sustainable economic growth.

AmCham EU has already met with a wide range of leading Estonian officials in Tallinn in March 2017 and will continue to meet with them in the coming months. In our initial discussions, it was clear that we share a number of policy objectives, such as the need to focus on the Single Market. We are convinced that Estonia will make progress and close several legislative files during its Presidency.

AmCham EU and its member companies stand ready to collaborate with the Estonian government and wish the Presidency every success.

Agenda for Action 2014-2019

The Agenda for Action offers ideas to enhance the competitiveness of Europe in the global economy.

AmCham EU calls for action in
five key action areas:



- 1 Build skills for the future**
- 2 Drive integration to create an attractive internal market**
- 3 Embrace revolutionary change for industrial leadership**
- 4 Develop new models of innovation and entrepreneurship**
- 5 Lead by example towards global integration**

Scorecard

AmCham EU uses these five key action areas to measure Europe's performance over time.

To learn more about AmCham EU's Agenda for Action Scorecard 2017, visit amchameu.eu/A4A17

Overall policy recommendations

- Uncertainty in Europe created by recent political events and by rising populism is a cause for real concern. EU leaders must act decisively to **bolster unity in Europe**, including by establishing a roadmap for more effective integration and placing greater emphasis on the **values and principles of the Single Market**.
- **Attracting the right talent and skills** remains a significant issue for businesses. This issue is likely to be compounded as the need for skills grows with increased digitalisation. The EU must place further emphasis on support for education and skills development, including early education, STEM skills, lifelong learning, and the portability of qualifications and professional standards.
- **Innovation** could be encouraged by a move towards greater technological neutrality, for example in public procurement. This would encourage competition and enhance efficiency.
- **Improving opportunities for entrepreneurship** and further encouraging innovation must be a priority. Currently, the outlook is mixed with new business ownership rates dropping in the past year. EU policy-makers should emphasise support for start-ups scaling up and in the event of bankruptcy. Greater access to finance for small businesses is also key.
- Europe retains a strong competitive advantage relative to much of the rest of the world. Nevertheless, concerns about insufficient **agility and flexibility in the economy** remain. Relaxing inflexible labour laws could be particularly helpful in addressing this issue.
- Europe's **commitment to free trade and open markets** is being openly challenged at home and abroad. A strong reaffirmation of the values and principles that underpin EU trade policy by EU leaders is critical to ensure the EU remains open for business to the rest of the world.

Policy recommendations by Council configuration

Agriculture and Fisheries

ISSUE

RECOMMENDATIONS

Agro-food supply chain

AmCham EU encourages the Presidency to take a holistic and coherent approach to any policy-making that impacts the food and agricultural sectors. Policies in other sectors should always take food security issues into consideration.

Discriminatory taxation in the agro-food sector

AmCham EU is concerned about policy proposals to introduce special taxes on certain food and beverages. Taxation is not an effective tool to tackle complex diet and lifestyle-related problems, and would particularly affect lower income groups. It would harm the European economy and the competitiveness of the food supply chain.

Revision of the legal framework for veterinary medicinal products

The veterinary medicines legislation should be based on sound benefit-risk assessment, not hazard-based approaches, and should modernise approaches to pharmacovigilance. Unnecessary and disproportionate administration hampering innovation should be reduced to encourage and enable new developments and to improve the functioning of the internal market. Investment in research is paramount to ensure that innovative treatments, new technologies and care options become available.

Risk assessment, management and communication in the agro-food sector

A proper balance between risk assessment, risk management and risk communication is crucial for the integrity of the food chain. Risk management decisions must be communicated in a clear and transparent way to help foster 'technology acceptance' amongst EU citizens. At the same time, the scientific and technical underpinning of risk management decisions must be demonstrated.

Sanitary and phytosanitary elements in trade and innovation policy

The divergence between the EU's approach to risk assessment, risk management and risk communication measures and that of its main trading partners leads to significant sanitary and phytosanitary questions in trade policy. It is of utmost importance to make progress in these areas, in particular with regards to plant protection products, maximum residue levels and agricultural biotechnology crops. A more effective and progressive regulatory framework is needed to address obstacles and promote innovative solutions.

Sustainability aspects of international trade in agricultural products

EU institutions are focusing on the sustainability of agricultural raw materials and the greening of supply chains. Therefore, environmental law-making is a potentially new non-tariff barrier to international trade. AmCham EU recommends addressing potential/current barriers through convergence and cooperation.

Competitiveness

ISSUE

Single Market

The EU Single Market is the basis of the economic success of Europe and a key determinate of US foreign direct investment in Europe. Completing the Single Market could help boost EU GDP by around four percent over the next ten years. It would increase productivity, investment and trade and job creation, helping to ensure Europe maintains its position as a global economic player.

Pressure on the Single Market has increased in recent months, particularly after the recent vote by the UK to leave the EU, as well as policy challenges such as migration, weak economic growth and an increasingly nationalised and fragmented EU decision-making process.

The will of EU policymakers to complete the Single Market is clear – as demonstrated by the Commission’s new Single Market Strategy released in October 2015. However, urgent action at member-state level is required. Strong member-state coordination and leadership, in partnership with the EU and stakeholders including the business community, is ultimately necessary for Europe to face head on its challenges and move towards a more effective Union and Single Market.

Industrial policy

To tackle the downward trend in investment in manufacturing in Europe, Member States should focus on implementing structural reforms. The right ecosystem for manufacturing includes solid infrastructure, great skills and talent, innovation, and labour flexibility at an affordable cost. Without the right environment, Europe’s industrial productivity and profitability level will not remain competitive in the global economy. The European Semester reports and recommendations should be fully leveraged at member-state level.

Better regulation

The better regulation agenda should remain a key priority of the Presidency, ensuring that key elements of the Inter-institutional Agreement on Better Law-Making are fully implemented. In this respect, particular attention should be devoted to the following areas:

- The introduction of transitional industry ‘lead-in’ periods following adoption of EU legislation;
- The need to increase transparency in the functioning of Commission expert groups;
- The importance of consulting stakeholders for their views when assessing if delegated or implementing acts should undergo an impact assessment; and
- The inappropriate use of soft law to extend the scope of binding provisions.

In addition, AmCham EU encourages the Presidency to support the Commission’s REFIT efforts to avoid overlapping legislation.

Competitiveness (cont.)

ISSUE

RECOMMENDATIONS

Compatibility of EU and US security programmes for customs

Mutual recognition between the authorised economic operator status (AEO) and the Customs Trade Partnership against Terrorism (C-TPAT) programme should be realised at the earliest opportunity. It should provide real benefits to business and should be used as the basis for all further mutual recognition agreements, thus providing business in the EU with standardised and harmonised procedures on a worldwide basis.

Defence industrial and procurement issues

European defence markets should be opened to allow the global defence industry to participate and to support efforts to foster increased transatlantic defence industrial cooperation.

The focus of the two Directives, 2009/81/EC on Security and Defence Procurement and 2009/43/EC on intra-community transfers of defence goods and services, should remain on efficiency and transparency in the European market and not on protectionist measures or the creation of additional barriers.

Energy costs

Addressing the wide impact of Europe's high energy costs should remain a top priority of the Presidency, with a focus on defining and rolling out concrete measures to support the competitiveness of the manufacturing industry in particular energy-intensive industries.

AmCham EU members in Europe have already significantly reduced their energy intensity. European manufacturing is already the least energy-intensive sector, and therefore the most energy efficient in the world. However, the price gap is such that 'the reduction was not large enough to offset price increase', as recognised by the Commission in its Competitiveness Report 2014.

The discrepancy in energy costs among the world's great regions should be addressed. Furthermore, the difference between electricity wholesale and retail prices can only be explained by distorting schemes, public interventions and tax levies on energy. EU institutions and national governments therefore have a role to play in addressing this discrepancy. AmCham EU believes it would be in the interest of both consumers and companies to create a common understanding of energy costs and to include a clear breakdown of taxes and levies in energy bills.

Promotion of intellectual property

The Presidency should support robust protection of intellectual property (IP) in both the online and offline worlds. World-class IP protection for all fields of technology, including the market-based development and deployment of these technologies is vital for maintaining European competitiveness. Protection of inventions, content (consistent with international agreements) and the fight against counterfeiting and piracy should be pursued in the EU and third countries.

Geo-blocking

Business-to-business must be excluded from the scope. Imposing such obligations undermines the established principle of contractual freedom between traders.

Clarity is needed on 'applicable law'. The current wording lacks legal certainty on liabilities in the case of a dispute with a consumer residing in a Member State where the trader is not directing its activities.

Institutions should review the potential interactions with sector-specific legislation to clarify the liabilities arising from the obligation to sell.

Economic and Financial Affairs

ISSUE

Transatlantic convergence in post-financial crisis financial services regulation

RECOMMENDATIONS

The global agenda regulatory reform in the wake of the financial crisis provides an unprecedented opportunity for coordination between EU and US policy-makers in financial services. Four specific issues act as a barrier to trade on EU-US financial services and need to be addressed as a matter of priority:

1. Extra-territorial application of rules: This can discourage third country investors from undertaking transactions that risk bringing them into the scope of the legal regime of a jurisdiction that is not their own, distorting economic decision making (e.g. the choice of counterparty) in a way that undermines market efficiency.
2. Divergent time lines for application: Greater attention needs to be paid to the timetables for the introduction of new rules stemming from the G20 and initiatives such as Basel III, to ensure that global markets are not disrupted by differentiated dates of application in different jurisdictions. Enough time should however be allowed to draw up well thought-through and calibrated rules and implementing measures..
3. Reciprocity provisions: We strongly encourage a political declaration by EU and US policy-makers to avoid including provisions requiring 'reciprocal' action by the other regime before market access is granted in future legislation.

Capital Markets Union

A well-functioning and appropriately regulated transatlantic capital market is key to driving long-term economic growth and competitiveness in Europe and the US. At present, the fragmented state of markets represents an obstacle to cross-border investments and the efficient allocation of capital.

While building a Capital Markets Union (CMU), it is crucial to keep important transatlantic and global financial markets into account, as well as the key roles played by non-EU investors into the EU, investment opportunities for EU investors and companies outside the EU and non-EU financial market participants in Europe. Moreover, in light of Brexit, the CMU will become an even greater priority for the EU.

A holistic approach to EU policy-making; facilitating long-term investment

We encourage the Presidency to ensure a holistic approach to EU policy-making. Legislation designed to restore market confidence should be consistent with EU goals to promote long-term investment. Initiatives aimed at facilitating access to finance should take existing financial services regulation into account and vice versa.

Economic and Financial Affairs (cont.)

ISSUE

Taxation policy

RECOMMENDATIONS

Financial Transaction Tax (FTT)

AmCham EU opposes proposals to introduce an FTT under enhanced cooperation. As proposed, an FTT will have serious implications, not just for financial institutions but for the 'real economy' – on businesses in every sector that legitimately use financial instruments in the normal course of their business, for example to manage risk.

International tax coordination

A unilateral EU approach to the direct taxation of multinational companies could create double-taxation problems and provoke concerns about protectionism if it is not coordinated with the ongoing multilateral tax discussion at the OECD level. The OECD is the best place for a coordinated and coherent approach to the taxation of multinational companies. A consistent adoption of the OECD's Base Erosion and Profit Shifting (BEPS) recommendations across the EU is a key priority. Going beyond the recommendations would negatively impact the EU's attractiveness for investment from EU and third-country companies alike.

Value Added Tax (VAT)

The Presidency has a role to play in fostering the debate and providing political guidance on the future of VAT. The revamped EU VAT system must be efficient and neutral for business and as robust and fraud-proof as possible, provided it does not impose a burden on taxpayers. The VAT Action Plan is an important aspect in that regard and should be promoted and implemented.

Employment, Social Policy, Health and Consumer Affairs

ISSUE

Challenges of work-life balance

RECOMMENDATIONS

To advance work-life balance, AmCham EU would welcome further EU-level policy guidance, strengthened monitoring, exchanges of good practices, and the development of meaningful benchmarks, monitored through the European Semester. However, we do not believe that there is a need to improve the EU-level legislative framework in order to address the challenges of work-life balance.

On gender diversity, a strict 'compliance' approach to diversity is not enough for businesses to reap the benefits of greater female participation. Public and private sectors need to partner in order to promote a balanced representation of both genders throughout an organisation's hierarchy, as well as encourage work-life balance. Organisations need to engage their leaders, both men and women. Simply implementing programmes for women or working parents is not enough and may even slow down their trajectory in the absence of proactive management.

Employment, Social Policy, Health and Consumer Affairs (cont.)

ISSUE

RECOMMENDATIONS

Labour market reform

The New Skills Agenda for Europe and the European Pillar of Social Rights provide the opportunity to implement labour reforms to ensure the long-term competitiveness of the European workforce through flexicurity measures and reforms to promote economic growth and labour markets agility. Policy frameworks must ensure a quick and smooth reallocation of resources, including human capital, from declining activities to emerging ones.

Implementation of the consumer acquis

AmCham EU welcomes the ongoing REFIT of the consumer acquis. We believe that the Presidency should focus on ensuring that existing consumer-related laws are transposed, implemented and properly enforced in national law before considering adopting new legislation.

Digital content

AmCham EU welcomes the proposal on digital content. However, work is needed to ensure that the proposed rules effectively deliver the promised benefits to consumers and traders. The introduced monetisation of data, which could impede rather than boost the data economy in Europe, is particularly alarming. We are also concerned by the disproportionate level of harmonisation. The relationship with other relevant existing rules should also be further assessed.

Online contracts

AmCham EU welcomes the initiative to improve the quality and coherence of European online contract law. However, the proposed directive lacks harmonisation with existing EU contract law, which will result in companies still relying on different rules for different distribution channels. AmCham EU urges the European institutions to ensure that the proposed directive is harmonised with the EU consumer acquis, and to wait for the conclusions of the REFIT exercise, which should clearly identify the gaps in consumer protection. This will help to ensure that the proposed rules facilitate easier online cross-border consumer transactions, benefitting business, consumers and society as a whole.

Discriminatory taxation on food and non-alcoholic beverages

Special taxes on certain food and beverage products are not an effective approach to tackling complex diet and lifestyle-related problems, and could be harmful to the competitiveness of the EU and national budgets. Given the discriminatory nature of food taxes on specific products, they must prove to be necessary, effective and proportional. As Member State taxes so far have not fulfilled these conditions from both socio-economic and public health perspectives, we encourage a re-evaluation of these proposals.

A strategic agenda for the life sciences industry

AmCham EU supports a strategic approach to life sciences – highly innovative industries such as pharmaceuticals, medical technology and e-health – to support growth and overcome health inequalities in Europe. The Presidency should consult industry and relevant stakeholders to define sector-specific actions aiming to boost the competitiveness of the healthcare industry in Europe, within the framework of the European Commission's industrial policy strategy.

In the face of demographic changes, constrained national budgets and increased international competition, AmCham EU proposes to establish a multi-stakeholder platform identifying inefficiencies in regulations and policies. We recommend that the European Commission adopts a broad approach towards a comprehensive life sciences strategy that allows recent innovative developments such as personalised medicine, data analytics, eHealth/mHealth and services to flourish.

Employment, Social Policy, Health and Consumer Affairs (cont.)

ISSUE

Investing in healthcare to build effective, accessible and resilient health systems

RECOMMENDATIONS

The fundamental link between better access to healthcare services and the uptake of healthcare innovation in Europe (improving health outcomes, ensuring that health budgets are sustainable and contributing to growth, competitiveness and job creation in Europe) risks being lost in the current economic climate.

In order to build safe, accessible and effective health systems and increase Europe's competitiveness, AmCham EU recommends to:

- Safeguard innovation by implementing dynamic efficiency policies that balance short term concerns (e.g. cost containment) with long term concerns (e.g. R&D investment);
- Provide smart regulations that are limited to their purpose;
- Avoid seeking economies at any costs, e.g. through promotion of economic-driven off-label use of medicines which can compromise patient safety;
- Support innovative partnerships between the public and private sectors;
- Take a consumer approach to empower citizens to be innovators in their own health; and
- Improve access to medicines through more flexible pricing policies such as differential pricing.

Access to medicines

AmCham EU believes that the issue of access to medicines should be part of a wider, strategic discussion aimed at achieving more effective and sustainable healthcare systems in the long term. Investment should focus on medicines' value and meaningful patient outcomes, and enable healthcare systems to adapt to the evolution of digital technology and other healthcare innovations.

To this end, AmCham EU calls for a broader view towards outcomes-based healthcare that provides:

- A holistic approach covering the whole spectrum of healthcare provision in relation to health outcomes;
- Resources and infrastructure to measure value and outcomes;
- Flexible frameworks to ensure fast access to medicines through innovative and alternative pricing schemes, such as differential pricing combined with the increased use of value-based pricing methods; and
- Strong intellectual property protection to increase access to medicines and incentivise their development.

Employment, Social Policy, Health and Consumer Affairs (cont.)

ISSUE

Public procurement of healthcare products (Implementation of Directive 2014/24/EU)

RECOMMENDATIONS

Public procurement can contribute to increasing the efficiency of national health systems by supporting the market uptake of innovative healthcare products, helping to address major societal challenges including ageing.

AmCham EU welcomed the 2014 revision of public procurement rules, including the new criterion of the 'most economically advantageous tender' (MEAT) in the award procedure, expected to make it easier for public authorities to put more weight on 'quality' or 'innovation' criteria relative to 'price'. However evidence collected by AmCham EU suggests that in many countries award criteria are still heavily price-biased even for complex medical devices or for pharmaceuticals for which interchangeability has not been established. In addition, processes and the lack of dialogue with bidding companies remain a challenge.

AmCham EU recommends to collect best practices and explore the opportunity of developing EU-wide guidance on the implementation of Directive 2014/24/EU and the procurement of healthcare products.

Pharmaceutical products and the Single Market

The Single Market should allow equal opportunities to patients to access appropriate treatments. The governance of pharmaceutical products must therefore be adapted to allow the Single Market to achieve its full potential.

Firstly, the inequalities in access to treatment must be addressed. Policies such as price referencing, i.e. External Reference Pricing, are preventing the full implantation of equity-based pricing between markets in Europe and causing inadequate management of drug shortages. Using cost containment as a guiding principle without considering the health impacts exacerbates this problem. One way to create a practical pricing framework is through the principle of non-extraterritoriality of medicine prices set by governments.

We also believe there should be a centralised authorisation procedure to switch appropriate medicines from prescription to non-prescription status. Legislation should be clarified to ensure that prior central authorisation does not prevent non-prescription status by national boards of health.

Medical devices and in-vitro diagnostics: making them safer and future proof

AmCham EU supports a modern and effective regulatory system for medical devices which ensures a high-level of patient safety while providing timely and continued access to the latest medical technologies. To do this the following is required:

- Maintain a decentralised authorisation system;
- Regulate the reprocessing of single-use devices;
- Increase harmonisation and coordination across Members States; and
- Increase transparency and better coordinate market surveillance across Member States.

Employment, Social Policy, Health and Consumer Affairs (cont.)

ISSUE

eHealth

RECOMMENDATIONS

AmCham EU believes that eHealth and mHealth are key enablers of more sustainable healthcare systems in Europe based on the exchange of electronic health information that will be highly personalised and focused on patient empowerment. In light of the transatlantic eHealth/health IT cooperation roadmap, efforts should be directed towards expanding the adoption of interoperable electronic health records and allowing citizens to access their medical information and related services online, including on mobile devices.

The steps undertaken as a result of the European Commission's consultation on its Green Paper on Mobile Health should lead to policies that engage citizens, healthcare providers and productivity vendors to enhance care outcomes, promote self-management, improve safety and lower health costs.

Environment

ISSUE

2030 climate and energy policies

(Also relevant for the Energy and Competitiveness Councils)

RECOMMENDATIONS

EU energy and climate policies must promote a balanced approach between the objectives of security of supply, sustainability and competitiveness to transition to a low-carbon economy at the lowest possible cost. In order to re-launch investments and drive the move towards a low-carbon economy, the EU must improve governance, clarity and predictability in both the ETS reform and the Clean Energy for All European Package.

Therefore, AmCham EU would encourage the Presidency to focus on:

- Completing the internal energy market;
- Ensuring a diverse mix of energy sources, including renewables, nuclear, coal and conventional and unconventional oil and gas;
- Leveraging the potential of energy efficiency, particularly in the building sector;
- Investing in infrastructure; and
- Integrating the external dimension of energy and climate policies.

Environment (cont.)

ISSUE

Emissions Trading Scheme (ETS) reform proposal

RECOMMENDATIONS

The ETS is the cornerstone of EU climate policy. The current proposal lacks key elements to support competitiveness and uncertainties arising from it may deter global business from investing in Europe, particularly given the absence of a credible carbon price trajectory. Ongoing discussions around the linear reduction factor do not provide any additional clarity: considering there is an international stock-taking exercise planned in 2023, AmCham EU believes there is no need to review the cap before this date, especially in the absence of any prior impact assessment. In addition, it should not be forgotten that the ETS only covers 43% of overall EU emissions and is only but one part of a global solution.

The current proposal does not reward best performers. A fixed flat rate reduction for benchmarks will impact all sectors equally regardless of their technology abatement possibilities and will penalise them. Benchmarks based on actual data would better reflect the improvement potential of each sector and avoid those side-effects.

Regarding the carbon leakage list, the pre-determined split between auctioned and free allowances rigidifies the whole system, while increasing the probability to trigger the C factor and therefore impact all sectors even the best performers. Enhanced flexibility should be found to ensure that any sector recognised as exposed to international competition receives as many allowances as it is entitled too. Moreover, the opportunity should also be given to any sector considering that its market conditions justify carbon relief, to reach out to the authorities and present its reasoning.

AmCham EU has consistently called for the compensation of ETS indirect costs. We support an effective and full compensation of indirect costs at the level of the best performers.

Finally, AmCham EU welcomes the Commission's efforts to increase investment in infrastructure through the Modernisation Fund as well as the broadened scope of the Innovation Fund. Nonetheless, greater clarity on how the funds will be governed and whether they will benefit industry projects is needed. As for the Innovation Fund, it is crucial to send a positive signal to investors, especially by increasing the maximum funding rate up to 75%, as suggested by the Parliament. In order to improve project risk management, it is also important that part of the funding is provided on achieving key intermediate (engineering) milestones, before the project is operational. Besides, the funding should go to projects that encourage a system approach and the progressive integration of the digital component. Prototypes should be eligible, as support in this phase is critical for technological development.

With regard to the Modernisation Fund, the tender process should be technologically neutral and not overly prescriptive. There should be complete transparency around the use of these funds and that this ETS-derived revenue is earmarked for low carbon investments. We also recommend compatibility across funds. To do so, we recommend the alignment of terms and conditions as well as the coordination of timelines.

Environment (cont.)

ISSUE

REFIT of the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH)

Endocrine disruptors

RECOMMENDATIONS

AmCham EU is an active stakeholder in the REACH regulation and has experienced its procedures first-hand.

Over the past few years, the implementation of REACH has improved and to some extent has become more predictable. The adoption of the Risk Management Option Analysis (RMOA) and of the Substances of Very High Concern Roadmaps are the most visible signs of such improvements. Nonetheless, AmCham EU believes more could be done to guarantee REACH delivers on safety without jeopardising competitiveness and innovation in Europe. The 2017 REACH evaluation is the perfect opportunity to do so.

As far as REACH is concerned, competitiveness is about much more than compliance costs. AmCham EU has noticed that too often the impact of REACH on industry is minimised to these costs only. AmCham EU recommends to take a close look at the impact of REACH on predictability and long-term investment in Europe; global competitiveness of Europe versus the rest of the world; and innovation.

AmCham EU is committed to the safe, environmentally-acceptable and sustainable use of chemical substances, including endocrine disruptors (ED).

Robust scientific evidence, fundamental principles of toxicology, full hazard characterisation and comprehensive risk assessments should be incorporated into the criteria for the identification of EDs. If not, many substances will be identified as EDs even though they present no risk for human health or the environment. This could have major unintended consequences for health, agriculture, trade, industry and the economy across Europe. However, substances identified as presenting an unacceptable risk should be subject to the appropriate regulatory action.

In that respect, AmCham EU considers the absence of potency and other aspects of hazard characterisation in the Commission's proposal to be a major omission. This will lead to the inappropriate identification of certain substances as EDs and ban many everyday substances such as vitamins, broccoli and soy protein, for example.

Environment (cont.)

ISSUE

Resource efficiency and the EU circular economy action plan

RECOMMENDATIONS

AmCham EU supports the underlying principles and objectives of the circular economy. Its members continuously work to develop and implement cost-effective and resource-efficient solutions, and have a proven track record of innovative developments. AmCham EU identified five key principles on which the EU circular economy should be built:

- More efforts need to be placed on consistent implementation across Member States and on developments of necessary infrastructure;
- A single market for secondary raw materials is critical to provide sufficient scale for the development of new business models;
- It is crucial to factor in the international dimension: EU circular economy strategy should create global loops rather than closing borders;
- A proportionate sharing of costs and responsibility along the value chain and waste management chain is essential; and
- There is no one size fits all solution and we support a sectoral approach to further promote the circular economy.

Waste Package

(including Waste Framework Directive, Packaging and Packaging Waste Directive, ELV and WEEE)

AmCham EU is a firm advocate of the further development of the circular economy. When they review existing or adopt new legislation in this field, EU policy makers should ensure that the smooth functioning of already successful industrial processes is not compromised. The Single Market is a strong asset in enabling the development of new, circular business models and it should be preserved. In this regard, AmCham EU suggests the following key recommendations:

Definitions

The waste package should set out clear definitions particularly when it comes to municipal waste, recycling, re-use/preparation for reuse and backfilling.

Targets

A sound, common methodology for calculating targets should be established. AmCham EU would rather focus on an overall (recycling) target for the circular economy without being too prescriptive on the ways to reach this target – e.g. no additional targets for the type of materials to be used like bio-based materials. Overly detailed and prescriptive targets could harm the market principle, as well as existing circular economy solutions and innovations.

PPWD legal basis

AmCham EU is concerned by the discussions around a potential change of legal base for the Packaging and Packaging Waste Amending Directive and the potential impact on the ability for packaged goods to move across the EU. Therefore we recommend to maintain a single market legal base.

Environment (cont.)

ISSUE

Waste Package

(including Waste Framework Directive, Packaging and Packaging Waste Directive, ELV and WEEE)

RECOMMENDATIONS

Extended Producer Responsibility (EPR)

The general requirements for the EPR should guarantee a level playing field and fair competition between the EPR schemes in all European countries, with a clear cost demarcation for producers.

End-of-waste

AmCham EU members encourage the Commission to set unambiguous definitions, as well as adopt necessary secondary legislation without delay to specify the end-of-waste criteria for different products, especially for those for which a strong demand exists. Existing end-of-waste criteria must be implemented consistently across Member States. AmCham EU believes that national end-of-waste criteria are not meaningful enablers of the circular economy, as they fragment the EU's market for secondary raw materials.

Waste and chemicals

AmCham EU cautions against addressing such a complex matter in the WFD, and stresses that existing chemicals legislation already addresses the concerns raised by the safe handling of chemicals. This is the case with product specific legislation, the Restriction of Hazardous Substances (RoHS) Directive for EEE, as well as with information obligations under the REACH Regulation.

General Affairs and Foreign Affairs

ISSUE

Brexit and EU-UK trade and investment relationship

RECOMMENDATIONS

The UK's impending withdrawal from the EU is raising important questions for the US business community in Europe. US companies – who are heavily invested in both the EU and the UK – require certainty about the path forward for the new EU-UK relationship. Significant disruption or changes to this relationship, or to the EU Single Market, could have profound effects on the ability of US companies to operate in these markets.

It is essential that the two sides deliver a new relationship that builds on the deep and comprehensive links that underpin EU-UK ties, while limiting disruption and uncertainty in the interim. Any agreement should preserve the integrity of the Single Market – the key driver for US investment. The American business community will be closely following the negotiations, and stands ready to provide constructive input to the EU and the UK throughout the process.

EU bilateral trade relations

The Presidency should support the early conclusion of free trade agreements that are:

- WTO-compatible;
- Ambitious in coverage;
- Balanced;
- Capable of strengthening and complementing the multilateral trading system;
- Contributing to the development of trade and investment friendly standards, rules and principles; and
- Promoting better protection of intellectual property rights.

The development of constructive dialogue with major trading partners at all levels is key to enhance mutual understanding, economic growth and prosperity.

Role of the World Trade Organization (WTO)

The renewed agenda at WTO level is a step in the right direction. AmCham EU values a strong WTO that acts as an important guarantor of legal rights in international trade and investment for business and society. Further market liberalisation and development of multilateral rules would boost global economic recovery for developing and developed countries alike.

AmCham EU calls on the Presidency to support the ratification and implementation of multilateral and plurilateral agreements including the Trade Facilitation Agreement (TFA), Trade in Services Agreement (TISA); and Environmental Goods Agreement (EGA), which could boost global trade and development.

General Affairs and Foreign Affairs (cont.)

ISSUE

RECOMMENDATIONS

Trade and investment

AmCham EU supports the Joint Statement of Shared Principles for International Investment agreed by the EU and US governments. AmCham EU calls on the Presidency to promote these principles, both within the EU and with third countries. Countries that apply these principles would significantly increase their chances of (re)building business confidence and attracting the investment needed to maintain and create sustainable jobs and prosperity.

Export control of dual-use goods

As cyber threats constantly evolve, heavy-handed regulation stifles innovative responses. Overly broadly labelling cyber surveillance technology as dual-use goods could undermine the ability of legitimate EU and foreign users of cybersecurity capabilities to protect themselves, without effectively deterring malicious parties from accessing harmful truly technological capabilities.

Industry is committed to thorough due diligence, but some of the proposed requirements could put a disproportionate burden on companies. A better balance of responsibilities should be struck between industry and national authorities, who are better equipped to gather intelligence on matters such as risks of human rights violations and terrorism.

As goods are traded at global level, export controls should be regulated at global level through multilateral forums (e.g. Wassenaar Arrangement). Going beyond these agreements will undermine EU competitiveness at an international level.

Enforcement of intellectual property rights (IPRs) in third countries

Improved protection of IPRs is crucial to encouraging innovation and building a European knowledge-based economy. Continued efforts to enforce IPRs in non-EU countries are essential for the EU and its Member States to compete in the global economy.

Review of the Privacy Shield agreement

The Privacy Shield agreement was an important step towards restoring much-needed certainty and confidence in conducting transatlantic business. This plays a key role in realising the Digital Single Market.

The Privacy Shield delivers strong protections for the personal data of European citizens and the agreement continues to be a success with over 1800 companies certified and hundreds of certifications currently under review.

A joint EU-US commitment is needed for a successful review of the Privacy Shield this year. The foundations of the agreement granted through the Presidential Policy Directive 28 regarding signals intelligence activities ('PPD28') and the Judicial Redress Act should not be altered.

Justice and Home Affairs

ISSUE

Data protection

RECOMMENDATIONS

AmCham EU believes that the GDPR does not take EU-wide harmonisation far enough. Harmonisation is especially crucial when taking situations such as the recently raised uncertainty on EU-US data transfer tools into account. A key concern is that different member states may take divergent views on particular aspects of the Regulation which could of course result in a patchwork of rules that GDPR aimed to prevent.

AmCham EU's member companies take GDPR compliance seriously, and are now working to implement the upcoming rules. When formulating guidance and rules on these and other issues, we encourage regulators to consult regularly and work closely with stakeholders, including industry, which will bear significant costs. AmCham EU has identified seven priority aspects where further guidance is needed: (i) the one-stop shop; (ii) high-risk processing / data protection impact assessments (DPIAs); (iii) personal data breaches and notification; (iv) approved codes of conduct and certification; (v) data portability; (vi) sanctions; and (vii) data protection officers (DPOs).

Integrated border management

It is key to strike the right balance between border security and the need for more efficient movement of travellers and the individual's rights and privacy. A clear EU legal framework for sharing, retaining and storing data related to border protection needs to be created. This will help companies to develop innovative technical solutions to meet security and data protection requirements.

Transport, Telecommunications and Energy

ISSUE

Energy Union Framework Strategy

RECOMMENDATIONS

Competitiveness

Energy and climate policies are and will remain highly interlinked with competitiveness and industrial policies. All industries operating in Europe should be allowed to compete, develop and innovate on a level playing field to ensure Europe's continued competitiveness, while transitioning to a stable low-carbon global economy. Both opportunities and risks for European business arise from this transition as well as global competition and they should be carefully calibrated. In this context, technological and tax neutrality should be the rule.

A more coordinated and regional approach to European energy policy, rather than fragmented national policies, is crucial. The proposed stronger governance process on energy policy as well as the upcoming 'winter package' are an opportunity to strengthen harmonised implementation of EU regulation.

Transport, Telecommunications and Energy (cont.)

ISSUE

Energy Union Framework Strategy

2030 Framework for Climate and Energy

Clean Energy for All Europeans Package

RECOMMENDATIONS

Infrastructure investment

Further developing energy grids, updating networks, addressing bottlenecks, deploying cross-border links, exchanging information on major national decisions and building new connections are crucial to delivering Europe's Energy Security Strategy and energy and climate objectives for 2030.

A well-functioning internal market

To complete a functioning, transparent and liberalised single energy market, a balanced approach should be promoted between the objectives of security of supply, sustainability and competitiveness to transition to a low-carbon economy at the lowest possible cost. Therefore, affordability of energy prices supporting industrial competitiveness as well as the moderation of energy demand should be a key dimension of the Energy Union, as outlined by Member States in October 2014.

Please see *Environment* section

AmCham EU welcomes the Commission proposal to restore market signals for the energy markets in Europe. A liberalised electricity market assumes the existence of a true, free flow of energy across borders. Only then can a market, based on full and open competition, deliver uninterrupted, competitively priced and secure energy. Among others, this requires enhanced European coordination and enlargement of cross-border grid capacities to further reduce the need for (national) capacities; increased transmission and strategic interconnector capacity to optimise allocation and congestion mechanisms, etc.

The new EU electricity market design should focus more on markets and less on regulation. To foster integration of renewables in the energy system, supporting the investments needed in infrastructure projects to integrate renewables, such as energy storage, should be the immediate political focus. To facilitate digitalisation of distribution systems, data collection and distribution must be given a greater role and data protection must be secured.

Competition and cost efficiency are paramount when renewables are promoted. This requires phasing out subsidies and shifting towards research and innovation for low-carbon technologies and storage.

Governance will be crucial to ensure the success of the package. Although targets help investment planning, the question of how EU-wide target will be implemented at national level remains and should be addressed. Therefore we welcome the proposal on governance.

Transport, Telecommunications and Energy (cont.)

ISSUE

Energy efficiency in buildings

RECOMMENDATIONS

Significant energy-saving opportunities exist in the building sector. Energy efficient renovation of existing building stock can generate cost savings for both public and private actors, increase energy security, create a significant number of local jobs and bring about a range of environmental benefits.

There is significant scope for improvement in several directives that are being reviewed as part of the Clean Energy for All Europeans Package: Energy Efficiency Directive (EED), Energy Performance of Buildings Directive (EPBD) and Renewable Energy Directive (RED). Particular attention should be paid to the implementation and enforcement dimensions. In addition, AmCham EU recommends setting an ambitious and clear vision for the EU building stock by 2050, with 2030, 2040 milestones.

In the short and medium terms, implementation and revision of existing EU legislation should support the synergies between EPBD, EED and RED. Upcoming revisions should also strengthen the existing legislative framework for buildings. In the longer term, the EU should support a more holistic, system-based approach that considers buildings as part of the energy system – balancing energy supply and demand, and where thermal networks and decentralised systems complement each other, providing more flexibility for an increased use of renewable energies. Equally important are efforts to promote financing and investment into energy efficiency in the buildings sector.

Security of supply and Liquefied Natural Gas (LNG) strategy

The safe and continuing supply of energy to Europe is crucial for the region's economic competitiveness and for attracting investment into the EU.

The proposed regulation for gas supply security should fully take into account the potential of indigenous energy sources. It would be a missed opportunity for the EU not to tap into the potential of indigenous European energy sources, including conventional and non-conventional oil and gas. As the proposal also puts the emphasis on transparency, AmCham EU is concerned that it could lead to companies having to disclose commercially sensitive information to the Commission.

The LNG strategy should remove obstacles to LNG imports, including from North America and newly discovered resources in the Eastern Mediterranean and North Africa, including all legal restrictions and non-tariff barriers to the import and export of oil, gas and coal in all their forms.

Transport, Telecommunications and Energy (cont.)

ISSUE

Low-emission transport

RECOMMENDATIONS

AmCham EU promotes five key principles to transition to a low-emission transport sector:

1. Support economic activity – Sustainability in transport can only be ensured if the social, economic and environmental dimensions are considered equally important. The potential of further completing the EU internal market for transport is enormous.
2. Address risks of climate change in an integrated and balanced manner – Policies should avoid market distortions and take a technology/fuel neutral approach.
3. Invest in infrastructure – Transport largely depends on further and accelerated investments in infrastructure, including Intelligent Transport Systems.
4. Maintain a level playing field between transport modes – All modes of transport will be needed to move the growing transport volumes of the future.
5. Factor in the international dimension of transport – Maintaining an international level playing field goes hand in hand with finding global solutions for global challenges.

Infrastructure: President Juncker's investment plan and EU project bonds

AmCham EU welcomes President Juncker's plan for investment and the set-up of a new European Fund for Strategic Investments (EFSI). AmCham EU equally supports the European project bonds and public-private partnerships. Well-managed pilot programmes can demonstrate the leverage factor and could significantly contribute to reversing the net decline in European investment over the last 30 years.

EFSI and EU project bonds are part of the toolbox but they cannot replace Member States' additional commitments and responsibilities for public investment and structural reform. They should also be supplementary to a strong European commitment to the completion of TEN-Ts/TEN-Es, a strong regional policy, an ambitious lending policy from the European Investment Bank and the earmarking of revenues.

None of these instruments should lead to financial market distortion or market access restrictions; they should support the EU's objectives while protecting the principles of technology neutrality.

Transport, Telecommunications and Energy (cont.)

ISSUE

Aviation strategy

RECOMMENDATIONS

AmCham EU recognises that aviation plays a crucial role in serving passengers and facilitating trade and tourism. Further liberalisation of international air service can lead to increased economic benefits. Therefore AmCham EU strongly supports the European Commission's Aviation Strategy for Europe.

The strategy should deliver on increased regulatory convergence and harmonisation with other regulatory authorities and international organisation, while considering conflicting EU policies such as chemicals policy and emerging technologies. The European Aviation Safety Agency (EASA) should retain a clear focus on existing responsibilities despite its expansion, in particular a timely, efficient, and risk-based approach to product certification and validation.

New security threats should be addressed through a risk-based approach to aviation supply chain security management and incentivise effective security screening technologies.

AmCham EU shares the sense of urgency on the need to implement more swiftly the Single European Sky and supports the implementation of a more efficient Air Traffic Management system. AmCham EU also promotes a measured, but effective, globally harmonised regulatory approach on the unmanned aircraft integration into civil airspace that focuses on safety and keeps up with evolving technology and market needs.

To deliver on the EU's ambitious climate objectives, the work of the International Civil Aviation Organization (ICAO) and the development of advanced biofuels will be instrumental.

Digital Single Market

It is critical to build a Digital Single Market of the next generation where connected machines and objects enable huge benefits for the economy and society.

As we connect more and more objects, it is crucial that policy-makers evaluate all existing tools and new market realities before deciding on policies, legislation or regulation. Analysis should be made of how these could impact digital innovation and transformation. Any policy actions - if needed - should be targeted, flexible, and future-proof. They must focus on synergies and measure the impact on the digital transformation of the European economy and its main industry sectors. Security and privacy policies will need to be optimised across borders to upscale technologies. Technology neutrality should be the cornerstone of policy-making.

Transport, Telecommunications and Energy (cont.)

ISSUE

RECOMMENDATIONS

Electronic Communications Code

AmCham EU supports the proposal for a new European Electronic Communications Code which gives Europe an opportunity to prepare for the future needs of the digital economy and society. However, AmCham EU believes the proposal could be more ambitious in terms of harmonisation in order to boost investment and innovation.

The European Commission's proposal rightly focuses on driving investments in world-class communications networks while at the same time maintaining the Significant Market Power (SMP) competition law based approach.

The proposals on spectrum are a step in the right direction, but should be considered as the minimum requirement, further alignment would be desirable in a world where everything will be increasingly connected wirelessly.

A more layered approach needs to be applied to services regulation. In order to enable a flourishing digital ecosystem, legislators should seek a horizontal as opposed to a sector-specific regulatory approach, and a harmonised, pan-European approach.

Finally, legislators should carefully consider to not create any unnecessary regulatory burden on the development of Internet of Things.

E-Privacy

We understand the need to ensure that European consumers are adequately protected in line with new tech developments but we are concerned that the proposed approach severely limits the potential of a data-driven digital economy, due to the possible overlap and duplication with existing regulations.

Overall, we are concerned that the approach to protect users from communication instead of ensuring the confidentiality of communications poses a major departure from the status quo and is unwarranted. In line with the draft Code, the EPR is also ambiguous with regards to M2M services (connectivity vs service).

To the extent the draft would nevertheless be maintained, we believe that the review of the ePrivacy Directive should be an opportunity to ensure full alignment with the GDPR.

Furthermore, in terms of the timeframe, political considerations should not override the adoption of a quality output. Business needs an adequate timeframe to implement this Regulation that would require significant changes to the business models that cannot be done within few months following the adoption.

Transport, Telecommunications and Energy (cont.)

ISSUE

RECOMMENDATIONS

Data economy

The data economy, and its benefits, requires significant and sustained private and public sector investment and innovation. The Commission should adopt a legislative proposal establishing the principle of free flow of data, making clear that regulatory obstacles to the free flow of data in the Union, both in national legislation and public procurement rules, are generally impermissible. Furthermore, AmCham EU does not see the need for introducing new policies in the emerging data economy to tackle identified “emerging issues”. Contractual solutions are sufficient to ensure parties’ interests are protected. While the data economy is still nascent, premature and overly-prescriptive intervention may chill, rather than encourage, innovation.

Cloud computing

AmCham EU strongly welcomes the European Commission’s plans to promote and accelerate the growth of cloud computing in Europe through initiatives set out under its Digital Single Market Strategy. Having the right regulatory framework in place allows the cloud ecosystem to thrive creates jobs and spurs growth. Cloud computing capabilities make it possible to tap into vast quantities of structured and unstructured data that can be used to extract business value and leverage the data economy. The cloud ecosystem of the future needs to be open, competitive, and secure, trusted by governments, corporations and consumers.

Cybersecurity/ Network and Information Security (NIS)

AmCham EU believes that governments and industry have a mutual desire to maintain and improve network and information security. Positioning the EU alongside its strategic partners and strengthening coordination between public-sector security institutions and conducting cyber exercises to improve preparedness is critical.

The EU should continue to engage proactively with international partners, especially the U.S. through the EU-U.S. cybersecurity dialogue, to advance cyber policy matters such as cyber norms, cyber defence as well as law enforcement cooperation in cyberspace at the intergovernmental level, to ensure that trust in the foundations of our connected world is not undermined.

The EU should focus on the harmonious implementation of the already existing regulatory instruments. All Member States should transpose and implement the NIS Directive as coherently as possible, to avoid raising or maintaining market barriers on the pretext of cybersecurity, and to do every effort to preserve and further strengthen partnership with industry and bi-directional sharing of cybersecurity relevant information and resources.

Europe should continue to build upon the positive experiences with public private partnerships, as collaboration and information sharing with the business community will be essential to build effective cyber resilience in pragmatic risk-based approaches.

Transport, Telecommunications and Energy (cont.)

ISSUE

Internet governance

RECOMMENDATIONS

The decentralised and multi-stakeholder process has enabled the Internet's evolution across the world and it will be crucial for the Internet's future success. Given the rapid pace of technological change, any framework for Internet governance needs to be guided by fundamental principles for international cooperation. To protect and preserve the economic and social opportunity made possible by Internet investment and innovation, it is absolutely crucial for the Internet governance process to be transparent and open to all stakeholders. Accordingly, multi-stakeholder organisations involved in Internet-related issues have shared characteristics, such as open stakeholder participation, consensus-based decision-making, information sharing, outreach and collaboration.

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AmCham EU speaks for

American companies **committed to Europe** on trade, investment and competitiveness issues. It aims to ensure a **growth-orientated business** and **investment climate** in Europe. AmCham EU facilitates the **resolution of transatlantic issues** that impact business and plays a role in creating **better understanding** of EU and US positions on business matters. Aggregate US investment in Europe totalled more than **€2 trillion in 2016**, directly supports more than **4.5 million jobs** in Europe, and **generates billions of euros** annually in income, trade and research and development.

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