

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

January - June 2017





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



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Malta assumes the Presidency of the Council of the EU for the first time since joining in 2004 and 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 first 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.

As European leaders are getting ready to celebrate the 60th anniversary of the Treaty of Rome, the voices of EU critics resonate loudly across the continent. They remind us that we cannot take the EU's achievements for granted. We need to get louder too, as we tell the story of Europe and what it brought to its citizens. With this in mind, we very much welcome the Maltese Presidency's focus on a well-functioning Single Market which ultimately benefits European citizens and businesses of all sizes alike. We are confident that the Maltese government will embrace this opportunity to demonstrate its leadership.

In an uncertain international environment, the case for strong transatlantic cooperation has maybe never been as compelling. 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 2015 and directly supports more than 4.3 million jobs in Europe. We look to the Maltese Presidency to be a strong supporter of the EU-US partnership.

We are looking forward to working closely with Malta before, during and after the Presidency to ensure we reach our common objectives of a stronger and more competitive Europe which creates jobs, meets consumers' needs and generates wealth for its citizens. This is why I am delighted to present these recommendations to the Maltese government on behalf of AmCham EU and our 165 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 Maltese officials in October 2016 in Valetta 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 Malta will make progress and close several legislative files during its Presidency.

AmCham EU and its member companies stand ready to collaborate with the Maltese 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

RECOMMENDATIONS

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.

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.

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 timelines 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 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

Climate change and 2030 Climate and Energy Roadmap

*(Also relevant for the
Competitiveness and Transport,
Telecommunications and
Energy 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 the governance, clarity and predictability of the 2030 Climate and Energy 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;
- 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. AmCham EU is concerned that the current proposal lacks key elements to support competitiveness and that the 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.

AmCham EU is concerned that 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, AmCham EU believes that a tiered approach overlooks the fact that companies are all part of the same value-chain and therefore interlinked. Such scheme would penalise the industry, including the sectors most at risk, rather than protecting it in an open and changing competitive environment.

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. 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 in the impact assessment. This is also important, in order to improve project risk management, 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 caffeine, 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:

1. More efforts need to be placed on consistent implementation across Member States and on developments of necessary infrastructure.
2. It is crucial to factor in the international dimension: EU circular economy strategy should create global loops rather than closing borders.
3. A proportionate sharing of costs and responsibility along the value chain and waste management chain is essential.
4. 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 and believes that the Single Market is a strong asset in enabling the development of new, circular business models. However, when reviewing existing and adopting new legislation in this field, EU policy makers should ensure that the smooth functioning of already successful industrial processes is not compromised. In this regard, AmCham EU suggests key recommendations:

Definitions

The waste package should set out clear definitions particularly when it comes to municipal waste, recycling, re-use and backfilling. AmCham EU is concerned by the introduction in the European Parliament's draft report of a definition of industrial waste while it remains unclear at this stage what this new definition will entail for industry, and in particular, how this new definition will apply when calculating the preparation for reuse targets.

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 – eg. 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.

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.

Environment (cont.)

ISSUE

Waste Package

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

RECOMMENDATIONS

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.

Finally, several issues should be addressed through the Action Plan, as originally planned by the Commission, instead of the Waste Framework Directive (WFD). This is for example the case for the presence of hazardous chemicals and for microplastics.

AmCham EU believes that the interface between chemicals and waste legislations needs to be discussed thoroughly and looks forward to engaging in the discussions planned on this topic in the circular economy Action Plan. 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.

AmCham EU recognises the importance of protecting the marine environment and supports efforts to reduce marine litter coming from plastics. Nevertheless, AmCham EU cautions against addressing this within the WFD, particularly with the Plastics Strategy coming up later in 2017.

General Affairs and Foreign Affairs

ISSUE

Brexit and EU-UK trade and investment relationship

RECOMMENDATIONS

AmCham EU is deeply concerned by the wave of disruption and uncertainty that the UK referendum result has sparked across Europe. A robust EU-UK trade and investment relationship is critical to Europe's competitiveness in the global economy.

As the future relations between the EU and the UK are being shaped, AmCham EU outlines its high-level principles for the upcoming Brexit negotiations:

- An ambitious deal that emphasises growth, investment and stability;
- Transitional arrangements to maintain continuity for business;
- Full access to each other's markets;
- Continued availability of skills; and
- A prosperous and stable EU.

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

Transatlantic Trade and Investment Partnership (TTIP)

AmCham EU strongly supports a robust TTIP agreement that will bring broad political, economic and geostrategic benefits to EU and US citizens. In light of a hostile political environment towards trade in Europe and the US, strong political support – especially by Member States – for the agreement must be maintained to ensure that a strong and ambitious TTIP is concluded in the near future.

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.

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.

Conflict minerals

AmCham EU supports a voluntary scheme with a focus on upstream of the supply chain where the difference can be made. Concentrating on upstream operators and on facilitating transmission of quality information in the supply chain will leverage the appropriate point in the supply chain. It is also consistent with the OECD Guidance and various industry initiatives, as well as complementing Dodd-Frank.

When trying to verify the source of minerals, the focus should be placed on smelters or refiners because they are the key point of contact in the minerals supply chain. AmCham EU also believes that a clear process and criteria for identifying conflict-affected areas should be defined and industry initiatives such as the CFSI should be recognised.

AmCham EU strongly supports the Presidency in concluding a practical agreement.

Justice and Home Affairs

ISSUE

Data protection

RECOMMENDATIONS

The General Data Protection Regulation (GDPR) misses its aim when it comes to striking the right balance between protecting personal data and promoting innovation through the free movement of data.

AmCham EU believes that the GDPR does not take EU-wide harmonisation far enough, and leaves too much space for Member State intervention. Harmonisation is especially crucial when taking situations such as the recently raised uncertainty on EU-US data transfer tools into account.

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.

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

Energy efficiency in buildings

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

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 will be reviewed shortly: 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 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.

Transport, Telecommunications and Energy (cont.)

ISSUE

Security of supply and Liquefied Natural Gas (LNG) strategy

RECOMMENDATIONS

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.

Low-emission transport

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.

Transport, Telecommunications and Energy (cont.)

ISSUE

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

RECOMMENDATIONS

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.

Aviation strategy

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.

Transport, Telecommunications and Energy (cont.)

ISSUE

Digital Single Market

RECOMMENDATIONS

The completion of the Digital Single Market is a key objective for future European growth. For the digital transformation of the economy to be successful, some essential elements need to be in place at various levels: technologies and data, trust, infrastructure, human/skills level and an enabling environment.

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. How regulators handle issues such as enabling international roaming and efficient numbering resources will have a significant impact. 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.

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. The focus on widespread access and take-up of very high-speed connectivity will allow Europe to remain competitive and attract more investment that will increase jobs and foster innovation and allow for more connected products that will improve all of our lives. However, AmCham EU believes the proposal could be more ambitious in terms of harmonisation in order to boost investment and innovation.

Broadband

AmCham EU supports a comprehensive policy approach to foster high investment levels in both fixed and mobile next generation access infrastructures. This is a prerequisite for Europe not to lag behind other parts of the world, thus maintaining a solid digital platform for innovation.

It is paramount that the telecoms framework is revised with this investment need in mind. This does not mean giving away on competition but rather finding a more appropriate balance between maintaining competition and creating stronger incentives for investment. The Commission's proposal goes a long way in finding that balance, maintaining the competition law based approach while trying to induce a more targeted approach and creating some new tools for driving new investment. The co-legislators should maintain this balance in the legislative process and ensure that any new tools, such as the co-investment proposal, remain open to and do not discriminate between different business models.

The Presidency should continue to encourage the targeted use of European and national funds to help finance the deployment of fixed and wireless broadband networks, in particular in rural areas where the business case for investment is weaker. Public sector funding should not create disincentives for private investment in new areas and/or distort competition in already competitive broadband markets.

Transport, Telecommunications and Energy (cont.)

ISSUE

Electronic Communications Code

RECOMMENDATIONS

Spectrum

With mobile broadband traffic growing exponentially, converged spectrum management should be seen as a priority. The potential of wireless broadband for closing the digital gap are tremendous, encouraging the emergence of new services and applications.

AmCham EU welcomes the European Commission's intention to increase convergence over spectrum allocation and calls the EU to be even more ambitious in order to be truly internationally competitive. The extension of licenses duration is crucial for creating the certainty and stability businesses require to invest. In this regard, the duration should be extended even beyond 25 years. Increased sharing will foster efficient use of spectrum.

It is also important that EU and US authorities coordinate and study measures for enabling the growth of the wireless sector, in particular looking into issues around innovation and freeing-up additional spectrum. Spectrum is the lifeblood of mobile Internet and supply is not keeping up with consumer demand. Access to more spectrum is critical to unleash the power of technology.

Services

Greater harmonisation and simplification are key to support investment, innovation and new developments in this specific market.

AmChamEU believes that a revision of the existing sector-specific rules on electronic communication services should focus on determining if regulation is still necessary: new realities need fresh thinking, not a reapplication of legacy rules. In that sense, the Commission may have missed an opportunity to create a new dynamic regime for all players to innovate and offer cross-border services on the basis of one single set of harmonised rules. Now we need to make sure that any new regulatory obligations are necessary, appropriate, technically feasible and conducive to the launch of new services. What we need is not just a targeted, proportionate and future proof set of rules but also one set of rules for all Member States.

AmCham EU appreciates the Commission's attempt to harmonise substantive provisions but regrets that exceptions are still too numerous. Furthermore, the review should be more ambitious in creating a clear distinction between residential and non-residential services and differentiate between different types of end-users. In this regard, the European Commission's proposal does not go far enough.

Transport, Telecommunications and Energy (cont.)

ISSUE

Cloud computing

RECOMMENDATIONS

AmCham EU calls on policy-makers to consider opportunities for facilitating responsible global information flows by evaluating interoperability of EU and US frameworks and by developing a global policy framework for the cloud. Greater harmonisation or interoperability across existing EU and global legal regimes will further enable businesses to adopt new technologies and implement new business models that can spur economic growth and provide societal benefit.

European and US companies have a substantial economic need for cross-border data flows between countries and regions with very different privacy regimes. An interoperable international privacy regime that recognises differing privacy rules (such as the US multi-stakeholder process) to the greatest extent possible, and honours these rules, would greatly accommodate companies operating in multiple jurisdictions and facilitate global economic growth.

Participation in international standards organisations and adoption of globally-accepted standards relating to cloud computing are important elements in ensuring that the full benefits of cloud computing can be realised.

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. The threat landscape is in constant evolution and the private-sector requires flexibility to respond without heavy-handed regulation stifling security innovation. The government has an important role to ensure that the legal framework is conducive to information sharing and recognising the global nature of cyberspace and framing policy accordingly. Positioning the EU alongside its strategic partners and strengthening coordination between public-sector security institutions and conducting cyber exercises to improve preparedness is critical. Governments need to adopt appropriate legal frameworks and provide resources to go after cybercriminals and undertake education and awareness activities to better inform and equip citizens and businesses.

With that in mind, AmCham EU urges the Presidency to encourage all Member States to transpose and implement the NIS Directive as harmoniously as possible, to avoid raising or maintaining market barriers on the pretext of cybersecurity, and to make every effort to preserve and further strengthen the partnership with industry and bi-directional sharing of cybersecurity relevant information and resources.

Moreover, AmCham EU remains concerned that upcoming European initiatives such as the contractual Public Private Partnership on Cybersecurity might not be as open, transparent and inclusive as we believe would be desirable in the interest of making Europe an attractive and world-leading region in terms of advancing global cybersecurity research, development and innovation.

Transport, Telecommunications and Energy (cont.)

ISSUE

Cybersecurity/ Network and Information Security (NIS)

RECOMMENDATIONS

Finally, AmCham EU is concerned about the recent European Commission proposal to revise the export control regulation. AmCham EU strongly encourages the Council to undertake in-depth consultations with relevant private sector and academia stakeholders on the creation or extension of any export control measures on cybersecurity-associated technologies such as intrusion and surveillance capabilities. Indeed, as illustrated by the difficulties that have arisen with the implementation of similar provisions introduced into the Wassenaar Arrangement in 2013, such measures need to be crafted and calibrated very carefully to avoid undesirable side-effects such as increasing legitimate technology users' exposure to cyber threats, hindering legitimate cybersecurity research, and preventing legitimate technology vendors from being able to improve the security of their products.

Internet governance

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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American business **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 2015**, directly supports more than **4.3 million jobs** in Europe, and **generates billions of euros** annually in income, trade and research and development.

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