



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

January - June 2019



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 2017**, directly supports more than **4.7 million jobs** in Europe, and **generates billions of euros** annually in income, trade and research and development.

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Secretariat point of contact:

Roger Coelho

Policy Director

RCO@amchameu.eu

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



Susan Danger
CEO,
AmCham EU

The Romanian Presidency of the Council of the European Union (EU) comes at a challenging and key moment for the future of Europe. This coincides with the European elections and institutional changes, the negotiations on the future EU-UK relationship and the decision in May on the multi-annual financial framework (MFF) post-2020. Therefore, the Romanian Presidency will assume an important role in framing the European agenda, and will need to make progress on key issues and priorities.

Political leadership will be critical to steering the EU in the right direction for 2019 and beyond, and the American Chamber of Commerce to the European Union (AmCham EU) stands ready to support Romania in this crucial role. One of the key priorities of the Romanian Presidency programme is to place European citizens' interests and aspirations at the core of policy-making. This will restore confidence in the EU's ability to deliver for its citizens and play a key role in promoting Europe on the world stage.

The EU and the US together are the drivers of global growth and, as global economic leaders, are bound by a common history, shared values and a commitment to our citizens. 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 2017, which directly supports more than 4.7 million jobs in Europe. These numbers demonstrate US companies' commitment to Europe and the fact that they are an integral part of communities across the continent. It is the collective responsibility of governments and business to ensure that continued investment in Europe benefits the people who work, live and want to raise a family here.

Creating jobs, meeting the needs of consumers and generating wealth for citizens will help to achieve our common objective of a stronger and more competitive Europe. This is why we are delighted to present these recommendations to the Romanian government on behalf of AmCham EU and our member companies. We hope they will provide concrete input and direction to the Presidency's work programme.

AmCham EU has already had the pleasure of meeting with a wide range of leading Romanian officials in October 2018 in Bucharest and will continue to engage with them in the coming months. In our initial discussions, it was clear that we share a number of policy objectives. We look forward to working closely with the Romanian government, and wish the Presidency every success.



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American companies invested in Europe

American companies have deep and longstanding ties in Europe. Along with creating jobs, developing infrastructure and driving innovation, American companies also invest in people and communities through social and educational programs, research and development or environmental and health initiatives.

Find out more about these investments and their social impact on the 'Invested in Europe: Our Stories' platform. It brings together initiatives led by U.S. companies tackling student poverty in France, building youth facilities in Bulgaria, creating low-emission mobility options in Belgium or developing new infrastructure for the Internet of Things in Germany.

Committed to Europe: Agenda for Action 2019-2024

The last five years have tested European unity and the post-war world order. From the Brexit vote to the rise of populism, the EU had to demonstrate its ability to take the lead and deliver for European citizens. As the effects of digitalisation and globalisation continue to transform our economies, societies around the world are pressured to become more resilient.

As American companies committed to Europe, the competitiveness of the region in the global economy is of utmost importance to us. Across Europe we play a key role in supporting and ensuring the prosperity of local communities, which together contribute to making a stronger EU that continues to be a powerful innovation hub and preferred investment destination.

With the 2019 European Parliament elections approaching, AmCham EU is faced with a unique opportunity to engage in the debate on the future of Europe and the EU's priorities for the next five years. Building on previous initiatives led in 2009, 2014 and before, the current document presents AmCham EU's vision for the upcoming legislative term.

This Agenda for Action outlines the four priority areas we believe should drive the political agenda over the next five years:



Empowering people

- Education
- Skills
- Inclusion



Leading global cooperation

- Transatlantic partnership
- Trade and investment
- Sustainability



Boosting the Single Market

- Smart regulation
- Better harmonisation and implementation
- Capital, digital, energy and transport



Investing in the future

- Human capital
- Research and innovation
- Infrastructure and best-in-class public procurement

Learn more: www.amchameu.eu/Agenda4Action

Policy recommendations by Council configuration

Agriculture and Fisheries

ISSUE

Revision of the legal framework for veterinary medicinal products

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

Reform of the Common Agricultural Policy (CAP)

RECOMMENDATIONS

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

A proper balance between risk assessment, management and communication is of paramount importance for the integrity of the food chain and in order to allow and promote innovation and sustainable growth in the food sector. We believe that risk management decisions should be communicated in a clear and transparent way to foster and encourage (rather than discourage) consumer acceptance of technological developments. Rigorous scientific and risk-based decision making should be at the front and centre of all discussions.

We believe that the EU should prioritise 5 principles in order to meet growing global demand for food while respecting the need to protect our plants and provide a future for European farmers.

1. Empower farmers through market driven policies, allowing them to respond to price signals while providing a safety net where necessary;
2. Protect the Single Market and retain commonality of the Common Agricultural Policy (CAP) – in view of the new architecture of National Strategy Plans;
3. Promote sustainable farming practices and productivity via sustainable intensification. This includes the promotion of clear incentives for vaccines and disease prevention practices as a sustainable tool to preserve the usefulness of antibiotics;
4. Support Research & Development (R&D) initiatives in agriculture including digital and precision farming; and
5. Promote a global playing field and nondiscriminatory treatment of local versus imported raw material needed to supply the European market.

Competitiveness

ISSUE

Single Market

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

Pressure on the Single Market has increased, particularly after the vote by the United Kingdom (UK) to leave the EU, in addition to policy challenges such as migration and an increasingly nationalised and fragmented EU decision-making process.

The will of EU policy-makers to complete the Single Market is clear - as demonstrated by the Commission's Single Market Strategy. However, urgent action at Member State level is required to ensure the integrity of this market in the long term, especially following the departure of the UK from the EU. Strong Member State coordination and leadership, in partnership with the EU, as well as key stakeholders and the business community, is necessary for Europe to be more effective and successful in facing new challenges.

Industrial policy

Europe faces increased global competition for investment. To tackle the downward trend of investment in manufacturing, Member States should focus on implementing structural reforms. We need the right conditions to ensure solid infrastructure, skills and talent, innovation and labour flexibility is at an affordable cost. The European Semester reports and recommendations should be fully leveraged at Member State level.

Centralised customs clearance and one-stop shop

All customs formalities should be handled through a single customs office in any EU Member State, rather than the current requirement to separately clear goods in all 28 countries.

Regulatory controls (eg, veterinary, phytosanitary and agricultural) should be managed through a single information technology (IT) interface used and recognised by all Member States. This will eliminate red tape, saving time and money, as goods will only be stopped once for checks.

Customs infringements and sanctions

Penalties for infringements should only be applied in cases of proven gross negligence or intentional fraud. These penalties should be levied on the basis of unpaid or underpaid duties, not on the value of the goods.

Both customs officials and companies need easily applicable and understandable rules which support and expedite trade rather than hamper it. They should serve as a tool, not an obstacle, particularly for Small and Medium-sized Enterprises (SMEs), which are the growth engines of the European economy.

Competitiveness (cont.)

ISSUE

RECOMMENDATIONS

Defence industrial and procurement issues

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

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 focused on efficiency and transparency in the European market and not on protectionist measures or the creation of additional barriers.

Supplementary Protection Certificate (SPC) for medicinal products

AmCham EU is concerned by the European Commission's proposal to introduce a manufacturing exemption ('waiver') to the Supplementary Protection Certificate (SPC) Regulation (EC) No 469/2009.

The SPC is an essential Intellectual Property Right (IPR) to support a vibrant biopharmaceutical sector in Europe. R&D based pharmaceutical companies provide direct benefits to patients, healthcare systems and economies through innovative treatment options, efficiency gains and high-quality jobs. SPCs partially compensate innovators for the substantial patent term lost between filing and the long clinical development and regulatory processes.

Though the Commission proposes a narrow and targeted exemption to SPCs to improve the generic sectors global competitiveness, the on-going legislative discussion indicates the potential further weakening of the EU's Intellectual Property (IP) incentives framework. This would clearly diminish the attractiveness and competitiveness of the EU as it would undercut pharmaceutical R&D investment by large and small innovators alike. By going backward on its efforts to become a knowledge-based economy, the Commission's proposal under discussion by EU legislators will potentially put R&D investments, high-quality jobs and significant trade surplus at risk.

We urge the Romanian Presidency to consider the impact of the proposal on international investment and medical innovation.

Enforcement of Intellectual Property Rights (IPR)

Strengthening the existing framework of IPR protection is an efficient way to secure innovation and investments in the EU. The protection of IPR will facilitate the creation of a safe and sustainable Digital Single Market.

The Commission's approach for increased cooperation among stakeholders (eg, through codes of conduct) and its commitment to a better enforcement of IPR within the Single Market, is a step in the right direction. The guidance on the implementation of the IPR Enforcement Directive (IPRED), published in November 2017, should assist in creating more legal certainty for all participants in the IP system and increasing consumer protection.

Tackling illegal content online (with regard to IPR infringements)

AmCham EU supports the Commission's objectives to address legitimate concerns around illegal content online and shares the view that this content has the potential to seriously compromise economic growth and jobs, as well as damage consumer protection and safety overall.

Competitiveness (cont.)

ISSUE

RECOMMENDATIONS

Unitary Patent (UP)

A fully functioning Unitary Patent (UP) system would signal that IP is a driver of innovation, competitiveness and growth for Europe in a global economy. We encourage Member States to ratify the agreement of the UP Court (UPC) to move forward with the implementation of the UPC and UP system.

Economic and Financial Affairs

ISSUE

RECOMMENDATIONS

Capital Markets Union (CMU)

While building a Capital Markets Union (CMU) it is crucial to take transatlantic and global financial markets into account. An open approach, ensuring that Europe maintains its access to global liquidity, would also go a long way towards realising the ambition of building a thriving EU capital market. Moreover, in light of Brexit, the CMU should become an even greater priority for the EU.

Risk reduction measures

AmCham EU supports rules which improve prudential requirements, recovery and resolution. Our overarching objectives are ensuring consistency with global standards and avoiding undue impediments to capital allocation. EU policy-makers should engage fully in the global rule-making process to ensure that the agreed standards meet their needs. The key to their success will be keeping the transatlantic and global financial markets in mind, while implementing the next iteration of prudential and resolution tools.

The Romanian Presidency should reconsider Article 21b of the Capital Requirements Directive V (CRD V), as currently drafted. The proposed EU Intermediate Parent Undertaking (IPU) structure would present many US banks operating in the EU with a potential legal conflict. These banks are subject to US structural requirements and limitations, severely restricting the market activities that can be conducted within the same corporate ownership chain. This also includes entities holding federally insured deposits.

Third country aspects of financial regulation

The CCP supervision proposal ('European Markets Infrastructure Regulation 2.0'), is one of the key aspects of a newly emerging EU approach on how financial firms access European markets from non-EU jurisdictions. However, this may have consequences for transatlantic relations.

We welcome the European Securities and Markets Authority's (ESMA's) improved supervisory role and the enhanced model of joint supervision for tier 2 CCPs. However, transatlantic relations and the EU-US markets may be strongly impacted if the EU approach involves negative recognition and forced relocation. To mitigate these risks, we believe the right way forward is to pursue the enhanced supervision for CCPs that are considered material for the EU, without a possibility of forced relocation and negative recognition.

Economic and Financial Affairs (cont.)

ISSUE

Third country aspects of financial regulation (cont.)

RECOMMENDATIONS

There is a close link with the third country aspects of the European Supervisory Authorities (ESA) review. AmCham EU supports the centralisation of power as long as it stimulates a model of 'supervisor/regulator of reference', which facilitates coordination of the transatlantic regulatory relation and brings clarity to the EU's diverse supervisory landscape. Policy-makers should use the drive towards supervisory convergence as a tool for the openness of the EU market and avoid it becoming a tool for fragmentation.

The perceived push against delegation, outsourcing and risk transfer arrangements to third countries is concerning. Restricting the ability to delegate portfolio management undermines the open nature of European funds frameworks and may hurt the attractiveness of the EU market, as well as its successful brand, the Undertakings for the Collective Investment of Transferable Securities (UCITS).

Taxation policy

International tax coordination: a unilateral EU approach to the direct taxation of multinational companies could create double taxation problems and reaffirm concerns about protectionism. Especially if it is not coordinated with the ongoing multilateral tax discussion at the Organisation for Economic Co-operation and Development (OECD) level. The OECD is the best forum for a coordinated and coherent approach to the taxation of multinational companies, and the 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.

Digital Tax: the taxation of the digital economy needs to strike the right balance between taxing value where it is creating and fostering growth.

A serious, structured conversation about how new business models should be taxed should take place in a multilateral context in order to ensure widespread agreement. The EU can bring valuable expertise, but there are concerns that the Digital Services Tax proposed by the Commission may make it more difficult for that process to succeed.

There are significant issues with the current proposals (especially a turnover-based tax), as they will probably reduce rather than promote the economic boost that digitalisation can bring. Turnover taxes substantially reduce the amount of company profits available for investment and reinvestment and could have a negative effect on jobs and growth in the EU.

Sustainable finance

We believe that it will be critical to leverage the experience of the private sector to support the transition to a sustainable economy. It is only with the help of the financial sector that we can meet the €180 billion annual funding gap to reach EU climate and energy targets.

Economic and Financial Affairs (cont.)

ISSUE

Sustainable finance (cont.)

RECOMMENDATIONS

To ensure the lasting success of the sustainable finance project, we believe the following principles will be crucial:

- **Regulatory certainty and economic stability:** it is essential that the EU ensures a coherent, holistic and long-term framework to promote sustainable growth, including clear and objective definitions of 'green', without which investors would lack regulatory certainty. In the interests of financial and economic stability complex default or market risk must be taken into account as a pre-requisite for sound action;
- **Evidence-based policy:** business is uniquely placed to provide expertise on the real-world challenges associated with climate change and the impact of transition orientated policy initiatives. Policy-makers should ensure that evidence drives decision-making and that all stakeholders are able to provide meaningful and substantive input; and
- **International openness:** the EU's leadership is critical to building international momentum on sustainable finance. However, we wish to stress that the ambitious energy transition targeted in the Paris Agreement requires the mobilisation of global financial markets. In line with the principles of the CMU, we recommend that EU initiatives take an open and outward-looking approach to ensure equal and non-discriminatory access for third country financial institutions, businesses and investors.

Employment, Social Policy, Health and Consumer Affairs

ISSUE

REFIT of consumer law

The Commission's efforts to improve enforcement of consumer protection rules are essential to safeguard consumers and ensure fair competition between traders in the Single Market. However, the proposal to introduce harmonised maximum penalties would fail to remedy the core of the issue, which is a lack of awareness of consumer rights and insufficient coordination between Member States.

Digital content

The proposal on digital content is a positive development. However, work is needed to ensure that the proposed rules effectively deliver the promised benefits to consumers and traders. Monetisation of data could impede rather than boost the data economy in Europe, and there are concerns on the disproportionate level of harmonisation. The relationship with other relevant existing rules should also be further assessed.

Sale of goods

The initiative to improve the quality and coherence of European contract law is a step in the right direction, particularly in light of the scope extension of the proposal to offline sales of goods. Nevertheless, the proposed directive remains uneven and the Romanian Presidency should seek to strike a better balance between consumers and traders.

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

ISSUE

RECOMMENDATIONS

Sale of goods

(cont.)

The Presidency should ensure that traders are protected from abuses, for example through the introduction and/or maintenance of notification obligations and the harmonisation period of the burden reversal from proof to six months. It should also guarantee that the proposed directive remains consistent with other policy priorities, including the Circular Economy and other elements of the consumer acquis, particularly the Consumer Rights Directives (CRD) and Digital Content Directive (DCD).

Health Technology Assessment (HTA)

AmCham EU supports the Commission's proposal on Health Technology Assessment (HTA), and its aim to harmonise the assessment of clinical evidence and avoid duplication of processes across EU Member States. We encourage the Romanian Presidency to adopt a balanced approach and methodology, to reflect the specificities of each sector of the healthcare industry, in line with the following recommendations:

- Increase alignment on clinical evidence requirements and generation in order to reduce duplication, pool expertise and speed up access to new pharmaceutical treatments, while preserving the Member States' autonomy to perform their own country-specific socio-economic appraisals and make decisions regarding pricing and reimbursement (P&R);
- Limit the scope of the Regulation to joint clinical assessment and scientific consultation for pharmaceutical products;
- Support the mandatory uptake of joint clinical assessments for pharmaceutical products; and
- Ensure cross-stakeholder consultation, including in the formal stakeholder network.

Improving access to health

AmCham EU supports the Romanian Presidency's focus on improving access to healthcare in Europe.

In order to build safe, accessible and effective health systems to reduce healthcare inequalities and boost the economy, we recommend to:

- Take a holistic approach to healthcare policy that accounts for the mix of services and products needed for treatment as part of an integrated life sciences strategy. Create the potential of budget headroom for innovation and to improve access by looking at the life cycle of health spending over a longer-term period;
- Safeguard innovation by implementing dynamic efficient policies that balance short-term concerns (eg, cost-containment) with long-term concerns (eg, R&D investment). Policies such as External Reference Pricing (ERP) which prevent the consolidation of equity-based pricing between markets in Europe, can result in inadequate management of drug shortages;
- Avoid arbitrary cost-containment measures that potentially limit patient choice and curtail safety standards and regulations (eg, through full-class tendering), or the promotion of economy-driven off-label use of medicines which can compromise patient safety;

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

ISSUE

Improving access to health

(cont.)

RECOMMENDATIONS

- Strengthen IP incentive frameworks to boost biopharmaceutical R&D;
- Support innovative partnerships between public and private sectors; and
- Take a consumer approach to empower citizens to be innovators in their own health (including through digital health solutions).

Fighting Antimicrobial Resistance (AMR)

We welcome the Romanian Presidency's aim to focus on the growing cross-border public health threat posed by Antimicrobial Resistance (AMR). The EU can and should serve as a leader in the fight against AMR, and the implementation of the 'One Health' Action Plan (linking animal and human health as well as environmental health), should be high on the list of priorities. We believe Member States should work together with the European Commission towards the following key objectives:

- Promote antibiotic stewardship to preserve the effectiveness of existing treatments;
- Expand and better coordinate surveillance tools and increase our knowledge of the mechanisms of resistance;
- Advocate for a broader and more effective use of vaccines and new technologies such as medical devices and diagnostics;
- Develop and implement new economic models and incentives to stimulate R&D in new antibiotics, vaccines and rapid diagnostics.

Digitisation of health

The Romanian Presidency's focus on the digitisation of healthcare rightly recognises the need to harness digital technologies to improve access and quality of treatment. Both electronic health (eHealth) and mobile health (mHealth) are key enablers of sustainable healthcare systems in Europe. They are based on the exchange of electronic health information, are highly personalised and focused on patient empowerment.

The steps undertaken as a result of the European Commission's April 2018 communication on the transformation of health and care in the Digital Single Market should lead to policies that engage citizens, healthcare providers and companies to enhance care outcomes, promote self-management, improve safety and lower health costs. 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.

Environment and Climate

ISSUE

EU strategy for long-term greenhouse gas (GHG) emissions reduction

RECOMMENDATIONS

The EU has taken a leadership role in climate policy, setting itself ambitious targets, and should use its position to leverage action with its main global partners to meet the Paris climate ambitions. Developing the 2050 strategy is clearly a challenging task which should start by ensuring that fundamental principles like technology-neutrality, predictability and transparency are encompassed in the existing and future regulatory framework.

Working on the following aspects would stimulate private efforts to reach the overarching objective:

- **Removing barriers:** implementing price signals and other regulatory tools will only be successful if investment in technologies is able to flow effectively. The EU and its Member States should target policy at removing barriers to technology, particularly looking at remaining administrative and regulatory barriers;
- **Encouraging sector coupling:** future changes to the energy system should be thought out in a holistic way. For example, electrification will increase the demand for power and require adaptations to the network. Furthermore, approaches should be fully integrated and holistic, drawing on the contributions of a wide range of stakeholders and solutions; and
- **Investing in labour:** the low-carbon economy will hinge on well-equipped and highly-skilled labour forces that are adapted to the needs of tomorrow. Educators and governments should work with business to increase the stock of future relevant skills.

Emissions Trading Scheme (ETS) reform proposal

As more focus turns to the implementation of the Emissions Trading Scheme (ETS), there is still room for improvement to support competitiveness and investment in Europe. Policy-makers should ensure a stable regulatory framework and prevent national interventions which distort market mechanisms.

AmCham EU recommends:

- Enhanced compensation of indirect costs for the industry; and
- Consistency between funds and clarity on the eligibility of industry projects to funding.

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

Over the past few years, the implementation of Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (REACH) has improved and to some extent become more predictable. The adoption of the Risk Management Option Analysis (RMOA) and of the Substances of Very High Concern (SVHC) Roadmap are the most visible signs in this sense. Nevertheless, more could be done to guarantee REACH delivers on safety without jeopardising competitiveness and innovation in Europe.

Several aspects of REACH could be improved to ensure a highly efficient system that is inclusive of all stakeholders and does not overburden industry:

1. Clarification of timelines for different REACH processes;
2. Avoidance of unequal treatment by Member State competent authorities when it comes to substance evaluations;

Environment and Climate (cont.)

ISSUE

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

RECOMMENDATIONS

3. European Chemicals Agency (ECHA) should not look to gather ‘data for data’s sake’;
4. Prevention of overlaps between the various REACH processes and sectoral policies; and
5. Authorisation streamlining and formalisation of the Risk Management Option Analysis (RMOA).

Competitiveness is about much more than compliance costs, and too often the impact of REACH on industry is minimised to costs only. A closer look should be taken at the impact of REACH on predictability and long-term investment in Europe, specifically when it comes to innovation and the global competitiveness of Europe versus the rest of the world.

Resource efficiency and the EU circular economy action plan

These five key principles should be the cornerstone of circular economy legislation as it moves forward:

1. More efforts need to be placed on consistent implementation across Member States and on developing the necessary infrastructure;
2. An effective Single Market for secondary raw materials is critical to provide sufficient scale for the development of new business models;
3. Factors in the international dimension: EU circular economy strategy should create global loops rather than close borders;
4. A proportionate sharing of costs and responsibility along the value chain and waste management chain is essential; and
5. There is no one size fits all solution, a sectoral approach will further promote the circular economy.

Plastics strategy and EU legislation on single-use plastics

The plastics strategy identifies policy options to increase the re-use and recycling of plastics in Europe. Material and technology neutrality, as well as a sectoral approach that does not fragment the Single Market will be paramount to its success. Product requirements vary from one sector to another and manufacturers should retain the ability to choose the best materials for their needs. To fully reflect the benefits that plastics bring to society the Commission should consider all stages of a product’s life cycle, including the use phase and the proper disposal of plastic waste.

Product bans or restrictions do not address the root causes of littering, as the problem is mainly the result of a combination of improper waste management and incorrect disposal behaviour. Single-use products have brought significant contributions to quality of life and even resource efficiency. In most cases, single-use items are an answer to market needs for hygiene, consumer safety, product preservation and practicality. When properly disposed of, these products can also be recovered at the end of their life cycle. Their positive contribution should not be discounted, however alternatives need to be encouraged so long as their environmental impact over the entire product life cycle is lower.

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 US companies, who are heavily invested in both the EU and the UK. Business needs 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 therefore essential that the EU and the UK agree on and ratify a Withdrawal Agreement before the March 2019 deadline. An orderly UK exit will avoid a damaging cliff edge scenario and precipitate a transition period which is essential for businesses to adapt to new requirements.

In the future, the two parties should be looking to agree a new relationship that builds on the deep and comprehensive links that underpin EU-UK ties, limits disruption and uncertainty, and preserves the integrity of the Single Market, which remains the key driver for US investment. Scoping for the future relationship should ideally begin as soon as a Withdrawal Agreement has been finalised. The American business community stands ready to provide constructive input to the EU and the UK throughout this process.

EU bilateral trade relations

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

- World Trade Organization (WTO) compatible;
- Ambitious in coverage;
- Balanced;
- Capable of strengthening and complementing the multilateral trading system;
- Contribute to the development of trade and investment friendly standards, rules and principles; and
- Promote better protection of intellectual property rights.

Constructive dialogues with major trading partners, including the US, are key to enhancing mutual understanding, economic growth and prosperity. US business in particular urges a de-escalation in the current transatlantic trade disputes which could threaten jobs and growth on both sides of the Atlantic.

Role of the World Trade Organization (WTO)

The current gridlock at the WTO is a cause for significant concern. A strong WTO 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.

The EU and its global partners should work to strengthen the principles of the multilateral trading system, through active participation at the WTO level. The EU should conclude multilateral and plurilateral agreements with global partners and promote the rule of law through a reinforced and fully functioning dispute settlement mechanism.

General Affairs and Foreign Affairs (cont.)

ISSUE

Export control of dual-use goods

RECOMMENDATIONS

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

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 the global level, export controls should also be regulated at this level through multilateral forums (eg, Wassenaar Arrangement). Going beyond these agreements will undermine international EU competitiveness.

Enforcement of IPR in third countries

The Commission's initiative to set up a Counterfeiting and Piracy Watch-list for marketplaces outside the EU is a step in the right direction. AmCham EU supports the Commission's approach to strengthen international efforts against counterfeiting and piracy and to encourage sustainable and meaningful actions to prevent IP violations throughout the global supply chain. Enforcement of IPR by the EU in third countries (eg, China, Russia, Ukraine, etc.), and greater cooperation between the EU and the US in the definition and implementation of IPR enforcement strategies needs to continue.

The Council should contribute to fight counterfeiting and piracy, in particular by promoting the activity of the European Observatory on Counterfeiting and Piracy.

Common Security and Defence Policy (CSDP) and the European Defence Action Plan (EDAP)

Systematic domestic preference for defence capability developments in Europe, justified by the notions of 'buy European' and 'strategic autonomy', will not only harm economic growth and transatlantic defence cooperation, but ultimately weaken collective security. The Commission's report on the implementation of two directives, Defence Procurement and Intra-Community Transfers and its recent European Defence Action Plan, are opportunities to remedy this by:

1. Creating an open EU procurement and funding process. Encouraging US defence industry participation to reinforce enhanced transatlantic defence industrial cooperation (TADIC);
2. Considering the footprint and contributions to the European Defence Technological and Industrial Base (EDTIB) of third country allied entities when participating in EU funded projects;
3. Implementing the Directives on Defence Procurement and Intra-Community Transfers with a focus on efficiency, transparency and avoidance of protectionist entry barriers;
4. Encouraging transatlantic cooperation through programmes that include US and EU partners to enhance interoperability and ensure operational superiority in the field; and
5. Streamlining bureaucratic processes to create a competitive transatlantic marketplace and foster a more efficient logistical supply chain process for industry and Member States.

Justice and Home Affairs

ISSUE

General Data Protection Regulation (GDPR)

RECOMMENDATIONS

The General Data Protection Regulation (GDPR) entered into force on 25 May 2018, but it remains a key concern for AmCham EU that it is applied in a uniform and balanced way at national level. We look forward to working together with the European Data Protection Board to ensure that guidance issued on implementing GDPR supports harmonisation across the EU and does not create uncertainties.

GDPR poses particular challenges for companies engaging in emerging technologies, such as Artificial Intelligence and Blockchain. Research and an inclusive debate on the application of the GDPR in those specific fields should be encouraged.

Integrated border management

The 2021 to 2028 Multiannual Financial Framework (MFF) proposal foresees nearly €10 billion for an integrated border management fund. The fund will aim to strengthen external border management, support Member States in securing EU's common external borders and finance new customs control equipment.

For integrated borders to become a reality, it is essential that a clear EU legal framework for sharing, retaining and storing data related to border protection is created. The certainty that this would provide will help companies develop innovative technical solutions to meet security and data protection requirements

Representative actions for the protection of collective interests of consumers

We support the Commission's efforts to facilitate access to justice and guarantee a high level of consumer protection. In some cases, it may be appropriate to achieve this through collective redress mechanisms. However, the proposal to introduce 'representative actions' does not include the full range of safeguards outlined in the Commission's 2013 recommendation to Member States. Without the full implementation of these recommendations, there is a serious risk that the EU will inadvertently introduce a US-style class action system, in which access to justice becomes a business, benefitting law firms and third-party funders rather than consumers.

Cross-border access to electronic evidence

The Commission's proposal provides a good basis to define a transparent and principled EU-wide framework, which can help further improve international cooperation. The EU legal framework should provide clear and efficient law enforcement procedures while ensuring strong safeguards. With the objective of creating a strong basis for a modern legal framework, we call on legislators to maintain and strengthen existing safeguards and procedures for users and providers. More importantly, an immunity for good faith compliance needs to be introduced for providers with time limits also reviewed. Furthermore, while central rules for handling conflicts with foreign law have been included, mechanisms to address conflicts of law need to be further developed. Lastly, we recommend to complement these proposals with government-to-government solutions and in particular a EU-US agreement.

Preventing dissemination of terrorist content online

AmCham EU takes interest in this proposal and is currently developing its position.

Transport, Telecommunications and Energy

ISSUE

Electricity market design

RECOMMENDATIONS

The new EU electricity market design should focus on markets and not on regulation. Adequacy assessments should be made at a regional level (ideally European), and look beyond generational capacity as well as considering auxiliary grid services and availability of short-term flexibility.

A market-driven energy policy where all technologies can compete on a level playing field is needed. Therefore we call for:

- The end of support schemes for mature technologies;
- Non-discriminatory grid network charges to be included in the legislation to allow a large-scale deployment of storage technologies;
- Scarcity pricing, which should help identify market mismatches;
- If required, that capacity mechanisms be temporary, regional and focused on safeguarding the security of supply at minimal cost to the consumer; and
- Flexibility to be rewarded.

CO₂ emissions standards for cars and vans

The transport sector is continuing its efforts in delivering emission reductions in line with the EU 2030 climate objectives. For policies in this area to meet their societal objectives, reduce emissions in transport and achieve the long-term climate change goals in a sustainable way, then EU industry competitiveness needs to be safeguarded and all stakeholders should be included.

Policies should meet several key conditions:

- Set an ambition level that ensures technological and economic feasibility, cost-efficiency and technology neutrality to reduce road transport CO₂ emissions effectively;
- Maintain the technology neutrality of the regulation, refrain from setting mandates or imposing a penalty for not reaching the low-emission benchmark;
- Distinguish the CO₂ reduction potential between passenger cars (PCs) and light commercial vehicles (LCVs) by creating separate feasible targets for each; and
- Recognise the untapped potential of other measures that can contribute to the reduction of CO₂ emissions in transport with an integrated approach. A long-term solution will need to focus on innovations in fuel, materials, vehicles and infrastructure technologies as well as non-technical measures and behavioural changes.

Infrastructure investment

The Commission's Investment Plan for Europe and the establishment and extension of the European Fund for Strategic Investments (EFSI) remains crucial. To keep Europe globally competitive, increased infrastructure funding is critical.

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RECOMMENDATIONS

Infrastructure investment (cont.)

The proposal to create a new 'InvestEU' umbrella fund will simplify and optimise access to this funding. As discussions progress, policy-makers should ensure that European infrastructure funding remains focused on promoting technology neutrality, co-modality and avoiding market distortion. Furthermore, funding at the EU level should be supported and complemented by ambitious commitments via Member States.

Digital Single Market

It is critical to build a Digital Single Market where connected machines and objects enable significant benefits for the economy and society. We need to focus on boosting investments in emerging technologies (eg, Artificial Intelligence, Blockchain and 5G) by removing market barriers, as well as creating a risk-willing environment to foster innovation and entrepreneurship.

As we connect more and more objects, policy-makers need to evaluate all existing tools and new market realities before legislating. Technology neutrality should be the cornerstone of policy-making.

Privacy and security are crucial for all stakeholders, and business understands its responsibility in building trust in the digital economy. These objectives should be implemented in a way that would not unnecessarily hamper innovation and growth. Furthermore, security and privacy policies will need to be optimised across borders to upscale technologies. Cross-border data flow is an essential condition for industries to grow across Europe and globally, be they small or large.

E-Privacy

AmCham EU is strongly concerned by the impact on digital innovation of the e-Privacy proposal in its current form. Alignment with the GDPR does not go far enough and recent text proposals put forward by past Presidencies continue to focus on regulating processing rather than on interference.

More flexibility is needed on the permitted processing of communication content and metadata. A technology-neutral approach is crucial and legislators should consider the impact of the suggested restrictions beyond cookies and browsers. The scope of the regulation remains problematic as it includes machine-to-machine communication, again creating less compliance certainty and potential burdens for many emerging and fast innovating sectors who would fall under such rules.

Artificial Intelligence (AI)

AmCham EU welcomes the comprehensive approach presented by the Commission on 25 April 2018 to unleash the development and uptake of Artificial Intelligence (AI) across Europe. Governments, companies and civil society should work together to ensure AI brings benefits to all citizens across Europe. Industry has a role to play in supporting the responsible development of AI. The Commission's initiative to bring stakeholders and expert groups together through the High-level Expert Group and 'AI Alliance', will be key in assessing the technology's impact and supporting its expansion. To foster the right policy environment, existing and new regulatory initiatives should be carefully assessed to avoid unintended consequences hindering AI uptake.

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RECOMMENDATIONS

EU Cybersecurity Act

Since cyber threats are global in nature, maintaining and improving international cooperation with public and private partners will remain essential to keep Europe safe, secure and resilient.

A stronger European Cybersecurity Agency (ENISA), and a more harmonised security certification framework, are key elements to ensure EU cyber resilience and to shape the future EU cybersecurity strategy. In the context of the on-going trilogue negotiations, AmCham EU has the following priorities:

- Take into account existing international standards and practices adopted by industry, as well as maintain a voluntary approach;
- Introduce a permanent Stakeholder Certification Group and ad-hoc committees, as proposed by the European Parliament;
- Assurance levels should not be limited to three and be clearly linked to assessment requirements, as proposed in the Council general approach. Self-assessment of conformity should be possible beyond the 'basic' assurance level;
- Ensure consistent security requirements. We are concerned by the language introduced in the European Parliament position on not-publicly known cybersecurity vulnerabilities disclosure procedures, and the obligation to issue a document on cybersecurity information.

European cybersecurity competence centre

We are concerned that the European Commission's proposal for a European Cybersecurity Competence Centre and Network would exclude non-European headquartered companies from partnership and funding. Furthermore, the future Centre and Network should build on a balanced governance system which also gives an important role to ENISA, ensures consistency in national chapters and contributes to on-going international work.

Directive on security of Network and Information Systems (NIS Directive)

The transposition and implementation of the Network and Information Systems (NIS) Directive should be as harmonious as possible. In proposing implementation acts, the light-touch approach agreed by the legislators should not be undermined.

Digital Europe funding programme (Multiannual Financial Framework)

We welcome the creation of a digital specific funding programme under the Multiannual Financial Framework (MFF) with the Digital Europe programme, including its objective to build Europe's leadership in technology by promoting investment, education and research in digital. Further clarity is needed on the concrete types of projects and the forms of funding.

We are concerned that some of the amendments included in the European Parliament's report and Council general approach undermine the collaborative approach as established by the Horizon 2020 and its predecessor programmes.

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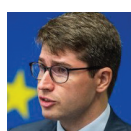


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amchameu.eu

American Chamber of Commerce to the European Union (AmCham EU)

Avenue des Arts/Kunstlaan 53, B-1000 Brussels, Belgium • amchameu.eu

T +32 (0)2 513 68 92 • F +32 (0)2 513 79 28 • info@amchameu.eu



American Chamber of Commerce to the European Union (AmCham EU)
Avenue des Arts/Kunstlaan 53, B-1000 Brussels, Belgium • amchameu.eu
T +32 (0)2 513 68 92 • F +32 (0)2 513 79 28 • info@amchameu.eu

